National Institute of Diabetes and Digestive and Kidney Diseases

NATIONAL DIABETES & DIGESTIVE & KIDNEY DISEASES

Advisory Council Orientation Handbook

January 2016

National Institutes of Health
U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Orientation for New Advisory Council Members

A MESSAGE FROM THE DIRECTOR, NIDDK

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is one of 27 Institutes and Centers that make up the National Institutes of Health (NIH), part of the Public Health Service in the U.S. Department of Health and Human Services. The Institute conducts and supports basic and clinical research in some of the most serious, common, disabling, and costly conditions affecting the public's health. The diseases in NIDDK's research mission cut across the full spectrum of medicine and include:

- Diabetes and other endocrine diseases;
- Cystic fibrosis and other inherited diseases;
- Digestive diseases;
- Obesity;
- Nutrition;
- Diseases of the kidney, genitourinary tract, and blood.

Most arise from the complex interaction of genetic, autoimmune, neuroendocrine, metabolic, nutritional, and environmental factors. Some diseases such as diabetes, obesity, hepatitis, and kidney failure disproportionately affect minority populations. NIDDK funds research projects that relate directly to these diseases, but it also places a high priority on fundamental, untargeted research.

Training is critically important to continued progress in medical research. NIDDK supports research training and career development, with special emphasis on increasing the ranks of physician scientists and recruiting underrepresented minorities and women into biomedical research careers.

The National Diabetes and Digestive and Kidney Diseases Advisory Council's most important purpose is to make recommendations regarding the funding of grant applications, focusing primarily on the relevance to the programmatic missions and priorities of the Institute. The Council also has the responsibility to ensure the adequacy of the scientific review by the initial review groups. In addition, the Council offers advice on a wide variety of policies and programs within the Institute.

As you begin service on the National Diabetes and Digestive and Kidney Diseases Advisory Council, we hope this orientation material will help answer some of your questions and provide the information you will need in your role as a Council member. In addition, your comments on the usefulness of this material and suggestions for improvement will be appreciated.

Griffin P. Rodgers, M.D., M.A.C.P.,
Director,
National Institute of Diabetes
and Digestive
and Kidney Diseases
National Institutes of Health

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NIH Gateway Center Map

Main Visitor Entrance: NIH Gateway Drive

Gateway Center - Building 66 (for pedestrians entering campus)

- Open Monday – Friday 6am – 10pm
- Closed on Weekends and Observed Holidays
- After 10pm weekdays, all day weekends and holidays, pedestrian visitors enter via Commercial Vehicle Inspection Facility (CVIF) – Building 67 (on Rockville Pike between North Drive and Wilson Drive)

Gateway Inspection Station - Building 66A (for vehicles entering campus)

- Monday-Friday: 5am – 10pm
  Weekends and after 10 pm: Closed
  After 10pm on weekdays, all day weekends, and holidays, visitors in vehicles should enter campus via the CVIF
- All vehicles and their contents will be inspected upon entering the campus.
- After inspection, vehicles enter campus at Center Drive
- Roadway at Center Drive is for entering campus only; visitors exiting campus may exit from other open locations.

Multi-Level Parking Garage 11 – MLP-11 (car inspection not required; visitor badges obtained at Gateway Visitor Center – Bldg 66) Hours: Monday - Friday: 6am – 9pm (entrance) 6am – 11pm (exit) Cost: $2 per hour for the first three hours, $12 maximum for entire day. Closed weekends.

Security Procedures for Entering the NIH Campus:

All visitors and patients – **please be aware**: Federal law prohibits the following items on Federal property: firearms, explosives, archery equipment, dangerous weapons, knives with blades over 2 ½ inches, alcoholic beverages and open containers of alcohol.

The NIH has implemented security measures to help ensure the safety of our patients, employees, guests and facilities. All visitors must enter through the **new** NIH Gateway Center and Visitor Center on Rockville Pike just south of the Metro station and previous visitor entrance at South Drive and Rockville Pike. **Except for persons parking in multi-level parking garage at the NIH Gateway Center (MLP-11)**, all vehicles entering the campus must submit to a vehicle inspection.

Whether arriving by Metro, hotel shuttle, or private or commercial vehicle, visitors over 15 years of age must show one (1) form of a government-issued photo ID—driver's license, passport, green card, etc**.** Visitors under 16 years of age must be accompanied by an adult.

Tobacco-Free Campus – Effective October 1, 2008, the use of all tobacco products (including cigarettes, cigars, pipes, smokeless tobacco, or other tobacco products) is prohibited at all times in all buildings; on all outside property or grounds, including parking areas; and in government vehicles.

Vehicle Inspections – Except for those parked in MLP-11, all vehicles and their contents will be inspected upon entering the campus. Additionally, all vehicles entering certain parking areas will be inspected, regardless of any prior inspection. Drivers will be required to present their driver's license and may be asked to open the trunk and hood. If you are physically unable to perform this function, please inform the inspector and they will assist you.

Vehicle inspection may consist of any combination of the following: Detection Dogs Teams (K-9), Electronic Detection Devices and Manual Inspection.

After inspection, you will be issued a vehicle inspection pass. It must be displayed on your vehicle's dashboard while you are on campus. The inspection pass is not a "parking permit." It only grants your vehicle access to enter the campus. You can only park in designated parking areas.

Personal Inspections – All visitors should be prepared to submit to a personal inspection prior to entering the campus. These inspections may be conducted with a handheld monitoring device, a metal detector and by visible inspection. Additionally, your personal belongings may be inspected and passed through an x-ray machine.

If driving onto campus, the personal inspection and issuance of a visitor badge will take place where your private or commercial vehicle (including a taxi) is inspected.

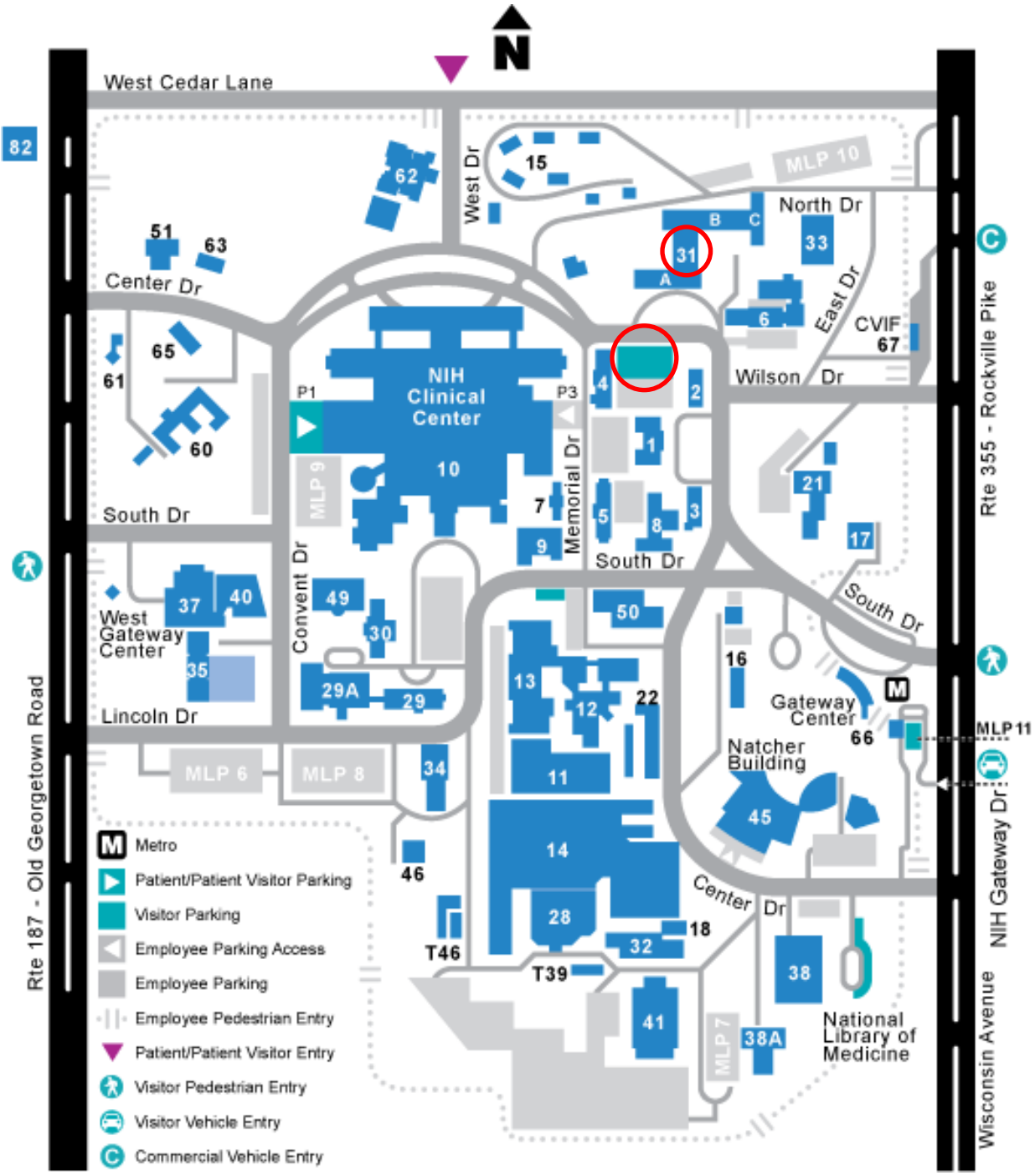
If you parked in the NIH Gateway Center multi-level garage (MPL-11), the personal inspection and issuance of a visitor badge will take place in the Visitor's Center. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://www.ors.od.nih.gov/pes/dats/nihshuttleservices/Pages/shuttle.aspx. Directional signs within Building 31 will guide you to the meeting room.

Visitor passes must be prominently displayed at all times while on the NIH campus.

To learn more about visitor and security issues at the NIH, visit: http://www.nih.gov/about/visitor/index.htm.

For questions about campus access, please contact the ORS Information Line at orsinfo@mail.nih.gov or 301-594-6677, TTY - 301-435-1908.

NIH Visitors Map of Campus



Street Address:
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

See Parking on Following Page

General Visitor Parking Information

Parking:

Visitors may park at the **Gateway Parking Garage (MLP-11)** (see Gateway Center Map) or in designated visitor parking lots (see Campus Map):

Monday – Friday, 6am – 9pm (entrance); 6am – 11pm (exit):
$2.00 per hour for the first three hours
$12.00 for the entire day

Metered parking lots:
Monday – Friday, 7am – 7pm
$2 per hour

Arriving at NIH:

When traveling to the main NIH campus, use of the Metro is strongly encouraged. Visitor parking lots on the NIH campus fill up quickly.

The NIH Has implemented security measures to help ensure the safety of our patients, employees, guests, and facilities. All visitors must enter through the NIH Gateway Center at Metro or the West Gateway Visitor Center. You will be asked to submit to a vehicle and personal inspection.

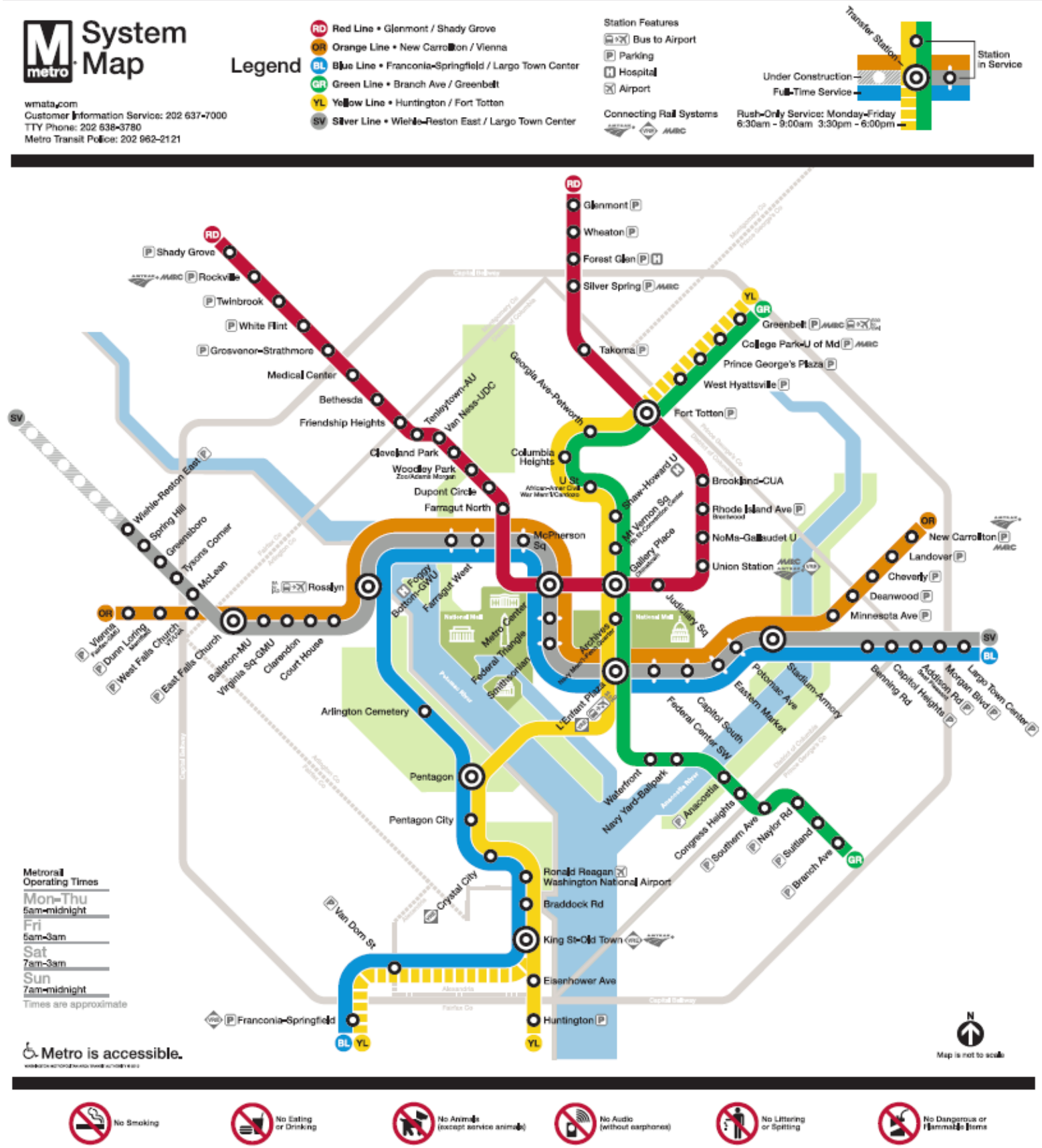
Visitors over 15 years of age must provide a form of government-issued ID such as a driver's license or passport. Visitors under 16 years of age must be accompanied by an adult.

If traveling via Metro or hotel shuttle to Medical Center Metro stop: The Washington D.C. Metro-Rail system Red Line has a station right on the NIH campus, called "Medical Center." Once you're out of the station, it's a short walk to the NIH Visitor Center where you will go through the NIH security procedures and receive a visitor's badge. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://www.ors.od.nih.gov/pes/dats/nihshuttleservices/Pages/shuttle.aspx. Directional signs within Building 31 will guide you to the meeting room

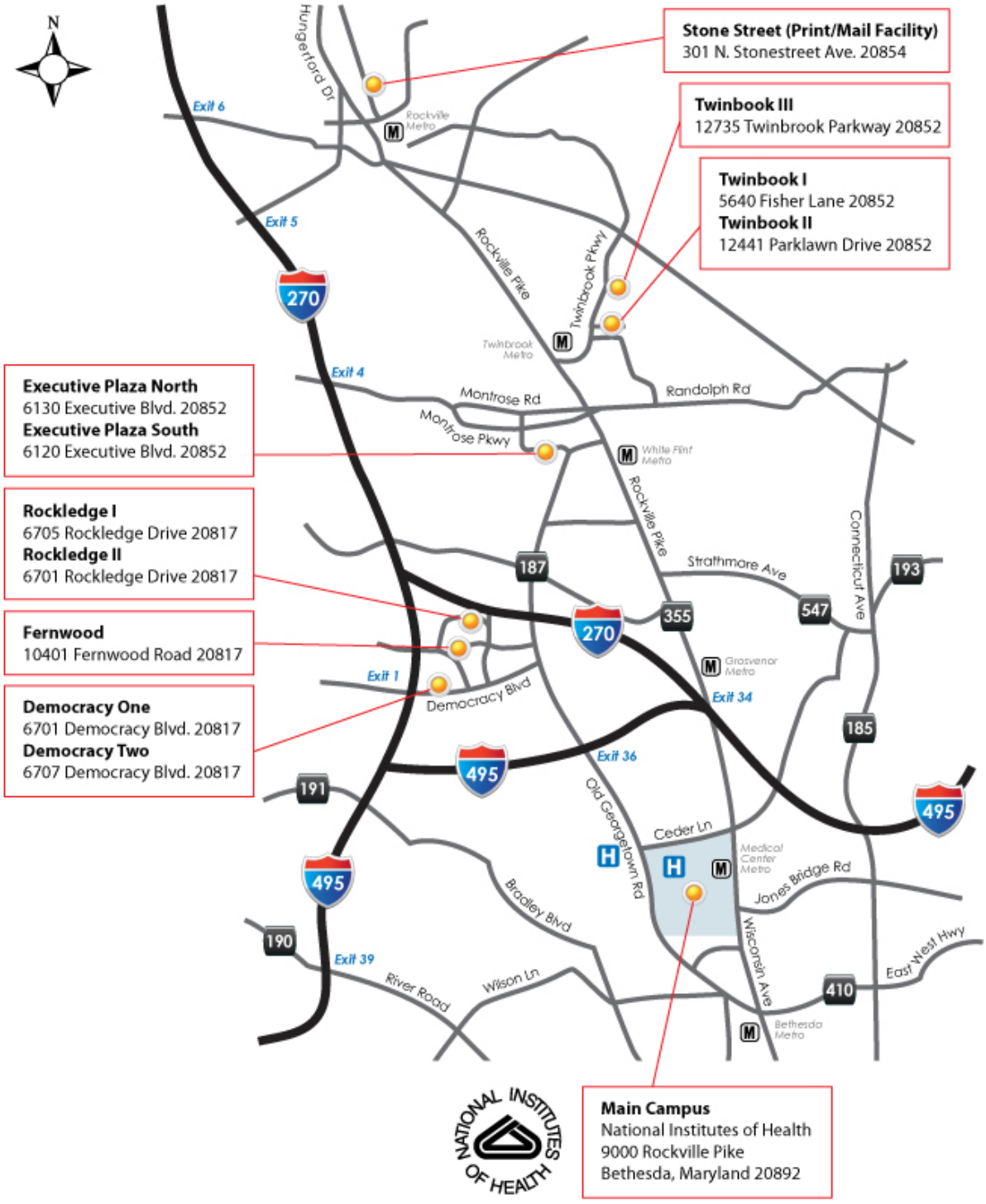
If taking a taxi directly to the meeting site: Upon entering the campus please let the driver know that you wish to be dropped off in front of Building 31. **The taxi must first go through an NIH security inspection of the car, and you and the driver must go through the security procedures and receive visitor badges**. Directional signs within Building 31 will guide you to the meeting room.

If driving private vehicle to the meeting site: Unless you choose to park in the NIH Gateway Center parking garage, receive your security processing at the Visitor Center, and take a shuttle to Building 31, you and your car must first go through security procedures. Visitor parking is located directly across from Building 31 (see **circles** on map). Parking fees are $12 per day and are fully reimbursable. Directional signs within Building 31 will guide you to the meeting room.

Vehicle and Visitor passes must be prominently displayed at all times while on the NIH campus.


System Map
Legend
RD Red Line • Glenmont / Shady Grove
OR Orange Line • New Carrollton / Vienna
BL Blue Line • Franconia-Springfield / Largo Town Center
GR Green Line • Branch Ave / Greenbelt
YL Yellow Line • Huntington / Fort Totten
SV Silver Line • Wiehle-Reston East / Largo Town Center
Station Features
Bus to Airport
Parking
Hospital
Airport
Connecting Rail Systems
Transfer Station
Station in Service
Under Construction
Full-Time Service
Rush-Only Service: Monday-Friday 6:30am - 9:00am 3:30pm - 6:00pm
wmata.com
Customer Information Service: 202 637-7000
TTY Phone: 202 638-3780
Metro Transit Police: 202 962-2121
Glenmont
Wheaton
Forest Glen
Silver Spring
Takoma
Greenbelt
College Park-U of Md
Prince George's Plaza
West Hyattsville
Fort Totten
Shady Grove
Rockville
Twinbrook
White Flint
Grosvenor-Strathmore
Medical Center
Bethesda
Friendship Heights
Tenleytown-AU
Van Ness-UDC
Cleveland Park
Woodley Park
Dupont Circle
Farragut North
Georgia Ave-Petworth
Columbia Heights
U St
Shaw-Howard U
Brookland-CUA
Rhode Island Ave
NoMa-Gallaudet U
Union Station
McPherson Sq
Mt Vernon Sq
Gallery Place
Judiciary Sq
Wiehle-Reston East
Spring Hill
Greensboro
Tysons Corner
McLean
Rosslyn
Foggy Bottom-GWU
Farragut West
Metro Center
Federal Triangle
Smithsonian
Archives
L'Enfant Plaza
New Carrollton
Landover
Cheverly
Deanwood
Minnesota Ave
Vienna
Dunn Loring
West Falls Church
East Falls Church
Ballston-MU
Virginia Sq-GMU
Clarendon
Court House
Arlington Cemetery
Pentagon
Pentagon City
Crystal City
Potomac Ave
Eastern Market
Stadium-Armory
Capitol South
Federal Center SW
Waterfront
Navy Yard-Ballpark
Anacostia
Congress Heights
Southern Ave
Naylor Rd
Suitland
Branch Ave
Benning Rd
Capitol Heights
Addison Rd
Morgan Blvd
Largo Town Center
Ronald Reagan Washington National Airport
Braddock Rd
King St-Old Town
Eisenhower Ave
Huntington
Van Dorn St
Franconia-Springfield
Metroral Operating Times
Mon-Thu 5am-midnight
Fri 5am-3am
Sat 7am-3am
Sun 7am-midnight
Times are approximate
Metro is accessible.
Map is not to scale
No Smoking
No Eating or Drinking
No Animals (except service animals)
No Audio (without earphones)
No Littering or Spitting
No Dangerous or Flammable Items

Bethesda Area Map Showing NIH Campus and Off-Campus Facilities



Glossary of Terms

For extensive list of grant terms see http://grants.nih.gov/grants/glossary.htm

A

Accession Number – Related to electronic submission of applications, the Accession number is the Agency tracking number provided for the application after Agency validations.

Acquisition – Obtaining supplies or services by the Federal Government with appropriated funds through purchase or lease.

Active Grant – A grant meeting the following criteria: (1) Today's date is between the budget start and end dates; (2) The grant has an eRA System (IMPAC II) application status code of "Awarded. Non-fellowships only." or "Awarded. Fellowships only."

Activity Code – A three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). *See* Funding Mechanisms in NIDDK section of Background Information.

Administrative Expenses – Expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

Administrative I/C – The NIH Institute or Center to which the Center for Scientific Review (CSR) routes NIH grant applications for a funding decision. An I/C may request to change this assignment if the application is more suited to another I/C. Also referred to as primary assignment.

Administrative Supplement – Monies added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.

Amendment (amended or revised applications) – Resubmission of an unfunded application revised in response to a prior review.

Appeal - A procedure for contesting the peer review of a grant application. Synonymous with rebuttal.

Application – A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions.

Application Identification Numbers – The application number identifies: type of application (1); activity code (R01); organization to which it is assigned (DK); serial number assigned by the Center for Scientific Review (CSR) (183723); suffix showing the support year for the grant (-01); other information identifying a supplement (S1), amendment (A1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number. *See* Sample Application Number Graphical Overview of Grants Process.

Application Types – Type 1, New; Type 2, Competing continuation (a.k.a. renewal, re-competing); Type 3, Application for additional (supplemental) support; Type 4, Competing extension for an R37 award or first non-competing year of a Fast Track SBIR/STTR award; Type 5, Non-competing continuation; Type 7. Change of grantee institution; Type 9, Change of NIH awarding Institute or Division (competing continuation.

Appropriation – Law authorizing Federal Agencies to obligate funds and make payments from the U.S. Treasury for specified purposes. Appropriations are in annual acts and permanent law.

Approved Budget – The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the Notice of Grant Award may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.

Award – The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

Awarding Office – The NIH I/C responsible for the award, administration, and monitoring of particular grants.

B

Bilateral Agreement – A general science agreement between the U.S. and a foreign country. Grant applications from institutions in these countries that have been recommended for approval by the scientific review group are given special funding consideration by Council.

Bridge Awards (R56) – Provides limited interim research support based on the merit of a pending R01 application while current researcher or new applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Investigators do not apply for Bridge Awards but are selected from R01 grants at the pay-line margin. A Bridge Award is made as an R56 with 1 year of funding, which the PI can choose to spend over a 2-year period. This enables the PI to submit an amended R01 application for the next receipt date while receiving interim (bridge) funding under the R56 mechanism. Interim funding ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

Budget Appropriation – The yearly amount given to a Government Agency by Congress.

Budget Period – The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

C

Career Development Awards (CDA K Series) – Award supporting Ph.D.'s and clinicians who wish to develop a career in biomedical research.

Capital Expenditure – The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient's regular accounting practices consistently applied regardless of the source of funds.

Clinical Research – Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies using human tissues not linked to a living individual.

Clinical Trial – A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g. 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects); Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety; Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use; Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Close Out – Procedure to officially conclude a grant. Institute staff must ensure necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy; includes the Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.

Co-Funding – Funding arrangement through which two or more Institutes or Centers pay for a grant.

Co-Investigator – An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS). Note: NIH does not recognize the term "co-PI."

Commitment Base – Funds used for non-competing (type 5 or ongoing awards), typically 70-80 percent of the dollars spent for research project grants.

Competing Applications – Either new or re-competing applications that must undergo initial peer review.

Competing Continuation – Application requiring competitive peer review and Institute/Center action to continue beyond the current competitive segment. (Also known as a Renewal or Type 2.)

Competitive Range – Contracting term denoting a group of proposals considered acceptable by the initial peer review group which are potential candidates for an award.

Concept – The earliest planning stage of an initiative [request for applications (RFA), request for proposals (RFP), or program announcement (PA)]. Concepts are brought before the Advisory Council for

concept clearance. Not all concepts cleared by Council are published as initiatives depending on the availability of funds.

Conflict of Interest – Regulations to ensure Government employees, scientific review group members, Council members, or others having the ability to influence funding decisions have no personal interest in the outcome.

Consortium Agreement – Formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.

Constant Dollars – Dollar amounts adjusted for inflation, based on buying power in a selected base year. The BRDPI is used to determine constant dollars from current dollars.

Contract (R&D) – Award instrument establishing a binding legal procurement relationship between NIH and a recipient obligating the latter to furnish a product or service defined in detail by NIH and binding the Institute to pay for it.

Contracting Officer – Government employee authorized to execute contractual agreements on behalf of the Government.

Cooperative Agreement (U Series) – Support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Council/Board, Advisory – National Advisory Council or Board, mandated by statute, providing the second level of review for grant applications for each Institute/Center awarding grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.

Council Round – At NIH, there are typically three council rounds each fiscal year: September. January/February, and May/June. Application receipt dates, initial review dates, and council review dates all fall within one of these council rounds. Incoming grant applications all are assigned to a council round.

Critique – An overall evaluation of a grant application prepared by a reviewer before an initial peer review meeting and presented to a Scientific Review Group at a meeting.

Current Dollars – Actual dollars awarded, without adjustment for inflation.

D

Direct Costs – Costs that can be specifically identified with a particular project or activity.

Direct Operations – Funds for salary and other administrative costs.

Dual Assignments – Applications simultaneously assigned to two Institutes, Centers, or Divisions. The primary Institute has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Dual Review System – Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an ICD's advisory Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.

DUNS Number – The Data Universal Numbering System (DUNS) number is a unique nine-digit number assigned by Dun and Bradstreet Information Services. It is recognized as the universal standard for identifying and keeping track of more than 92 million businesses worldwide. Grants.gov requires a DUNS number for registration. For applicants, the DUNS number in the application must match the DUNS number in the Institutional Profile in Commons.

E

Early Stage Investigator (ESI) – A New Investigator (*see* definition under N) who is within 10 years of completing a terminal research degree or within 10 years of completing medical residency. Between 1980 and 2001, the duration of postdoctoral training increased and the average age at which an investigator first obtained R01 funding increased by more than 5 years. Under the ESI program (NOT-OD-08-121 released September 26, 2008), New Investigators identified as ESIs will have their career stage considered at the time of review and award of R01 applications. By providing this advantage to ESIs, NIH can directly encourage earlier application for NIH research grant support. In some cases there may have been one or more lapses in the period of research or research training after the terminal degree or completion of medical residency. A new NIH Guide Notice (NOT-OD-09-034, released December 31, 2008, by the Office of Intramural Research) describes the procedures for requesting an extension of the ESI period and the conditions under which such extensions can be considered.

Electronic Research Administration (eRA) – NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. Registration is required.

Enrollment Data – Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began. This data is provided in competing continuation applications and annual progress reports.

Equipment – An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less.

eRA Commons – A secure meeting place on the Web where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants. Registration is required. At this site applicants access the status of their applications and grantees access the status of their awards, submit reports, and make requests electronically

Expiration Date – The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Extramural Research – Research supported by NIH to researchers and organizations outside the NIH through a grant, contract, or cooperative agreement.

F

Facilities and Administrative Costs (F&A) – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "indirect costs."

Federal Acquisition Regulations (FAR) – Laws regulating government contracting.

Federal Advisory Committee Act (FACA) – A law regulating Federal advisory committees to ensure an appropriate balance of scientists and lay persons and minority, geographical, and racial representation.

Federal Register – An official, daily publication communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance.

Federal-Wide Assurance (FWA) – Online form every institution and collaborating institution conducting human subjects research must file with the Office for Human Research Protections—HHS to establish policies and procedures to protect human subjects as required by 45 CFR 46.

Fee – An amount (in addition to actual, allowable costs) paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as “profit.”

Fellowship - An NIH training program award where the NIH specifies the individual receiving the award. Fellowships comprise the F activity codes.

Fiscal Year (FY) – The annual period established for Government accounting purposes. A Fiscal Year begins on October 1 and ends September 30 of the following year. Example: FY2009 – Started October 1, 2008 and ends September 30, 2009.

Full-Time Appointment – Number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

Funding Opportunity Announcement (FOA) – *See* Initiative.

G

Gender – Human subject term indicating a classification of research subjects into women and men.

Grant – Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grant Appeals – A DHHS policy providing for an appeal by the grantee institution of post award administrative decisions made by awarding offices. The two levels of appeal are an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.

Grant Project Period – Total period a project has been recommended for support, which may include more than one competitive segment. For example, a project period for a grant begun in 2008 can be divided into competitive segments 2008 to 2012, 2012 to 2016, etc.

Grant Start Date – Official date a grant award begins; same as the first day of the first budget period.

Grantee – Organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Grants Management Officer (GMO) – An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH Institute and Center awarding grants has one or more GMOs with responsibility for particular programs or awards.

Grants Management Specialist (GMS) – An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.

Grants.gov – An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for more than 1,000 competitive grant opportunities from the 26 Federal grant-making Agencies. The Department of Health and Human Services (DHHS) is the managing partner for the Federal Grants.gov initiative, one of 24 initiatives of the overall E-Government program for improving access to Government services via the Internet. Registration is required to apply. Go to http://www.grants.gov/.

H

High Risk/High Impact (HR/HI) – A category of applications identified by a scientific review group as having a high degree of uncertainty in approach but also a high potential for impact. NIH tracks how many of these applications are identified and funded.

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.

Human Subjects Assurance – A document filed by an institution conducting research on human subjects with the Office for Human Research Protections—HHS that formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding.

I

Identifier – Information linking specimens or data to individually identifiable living people or their medical information. Examples include names, social security numbers, medical record numbers, and pathology accession numbers.

Indirect Costs – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "Facility and Administrative Costs."

Information for Management, Planning, Analysis, and Coordination (IMPAC) – A computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs.

Informed Consent – Person's voluntary agreement, based upon adequate knowledge and understanding, to participate in human subjects research or undergo a medical procedure. In giving informed consent, people may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence.

Initial Peer Review Criteria – *Significance:* Is the topic important? Will it advance Scientific Knowledge? ***Approach:*** Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed? ***Innovation:*** Does the proposal involve new ideas or methods; does it challenge existing paradigms? ***Investigator:*** Does the investigator and collaborators have the training and experience to do the work? ***Environment:*** Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations? Note: criteria-based scoring commences in 2009.

Initiative – A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating the Institute or Center's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not. *See* Funding Opportunity Announcement (FOA)

Institutional Base Salary – The annual compensation paid by an applicant/grantee organization for an employee's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

Institutional Review Board (IRB) – IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under their auspices. IRBs make an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.

Interactive Research Project Grant (IRPG) – An award made to two or more investigators funded independently as R01 grantees but brought together as a collaborative group receiving additional support for collaborative work, shared resources, or the exchange of ideas.

Interagency Agreement – Formal agreement among Government agencies to collaborate on and fund research; Y series activity code.

Integrated Review Group (IRG) – A cluster of study sections responsible for the review of grant applications in scientifically related areas. These study sections share common intellectual and human resources.

Internet Assisted Review (IAR) - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing. Allows Reviewers, SROs, and GTAs to view all critiques in preparation for a meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRO or GTA.

Intramural Research - Research conducted by, or in support of, employees of the NIH.

Investigational New Drug (IND) – Status given by the FDA to a new drug or biological product to be used in a clinical investigation.

Investigator-Initiated Research – Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees. Its opposite is targeted research.

J

Just-In-Time – Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred. Through this module, institutions can electronically submit the information that is requested after the review, but before award.

K

Key Personnel – The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. “Zero percent” effort or “as needed” is not an acceptable level of involvement for key personnel.

M

Matching or Cost Sharing – The value of third party in-kind contributions and the portion of the costs of a federally assisted project of program not borne by the Federal Government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH Institute or Center. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

Mechanism – Another term for Activity Code.

MEDLINE - National Library of Medicine's database for scientific publications.

Minority Group – Human subject term indicating a subset of the U.S. population distinguished by racial, ethnic, or cultural heritage. Categories are: American Indian or Alaskan Native, Asian, black or African American, Hispanic or Latino, and Native Hawaiian and other Pacific Islander. Inclusion of a group should be determined by the scientific questions under examination and their relevance. Not every study will include all minority groups or subpopulations.

Model Organism – Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms.

Modular Application – A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

Monitoring – A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

Multiple Principle Investigator – Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution.

N

New Application (award, grant) – Refers to an application not previously proposed, or one that has not received prior funding. Also known as a Type 1.

New Investigator – New investigator is an individual who has not previously competed successfully for an NIH-supported research project other than the following small or early stage research awards: Pathway to Independence Award-Research Phase (R00); Small Grant (R03); Academic Research Enhancement Award (R15); Exploratory/Developmental Grant (R21); Clinical Trial Planning Grant (R34); Dissertation Award (R36); Small Business Technology Transfer Grant-Phase I (R41); Small Business Innovation Research Grant-Phase I (R43); Shannon Award (R55); NIH High Priority, Short-Term Project Award (R56). Additionally, an individual is not excluded from consideration as a "New Investigator" if he/she has received an award from the following classes of awards: Training-Related and Mentored Career Awards; Fellowships (F05, F30, F31, F32, F34, F37, F38); Mentored-career awards (K01, K08, K22, K23, K25, K99-R00; Other mentored career awards (developmental K02 as used by NINDS and the developmental K07); Loan repayment contracts (L30, L32, L40, L50, L60). Note: Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are not considered new investigators. *See* Early Stage Investigator.

Non-Competing Continuation – A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review but are administratively reviewed by the Institute/Center and receive an award based on prior award commitments. Also known as a Type 5.

Non-Competing Grant – An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Notice of Award (NoA) – The legally binding document notifying the grantee and others that an award has been made. The NoA contains or references all terms and conditions of the award documenting the obligation of Federal funds and may be in letter format and may be issued electronically. Previously known as Notice of Grant Award (NGA).

Not Recommended for Further Consideration (NRFC) – A judgment made by a scientific review group for applications when the merit of the proposed research is not significant and substantial enough to warrant a further review. The study section does not recommend funding; the application cannot be funded by an Institute.

O

Obligation – Data based on NIH funds that have been awarded by an NIH Institute/Center.

Office of Extramural Research (OER) – NIH office overseeing policies and guidelines for extramural research grants.

Office for Human Research Protections (OHRP) – HHS office overseeing human subject protection for HHS-supported research.

Office of Laboratory Animal Welfare (OLAW) – NIH office overseeing compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Office of Management and Budget (OMB) – Executive Branch office assisting the U.S. president in preparing the Federal budget, evaluating agency programs and policies, and setting funding priorities. In setting policy, OMB issues Government-wide policy directives, called circulars that apply to grants.

On Time – Paper applications using "standard" submission dates are on time if postmarked on or before the submission date. Electronic applications are on time if successfully submitted to Grants.gov by 5 p.m. local time on the date indicated. Note: For both paper and electronic submissions, when these dates fall on a weekend or holiday, they are extended to the next business day.

Organization – A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.

Organizational Code – A two-letter code in the grant number identifying the first major-level subdivision of the funding organization. NIDDK's organizational code is DK.

Other Research Grants – Research grants not classified as research projects or research centers.

Other Support – Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.

Overlap of Support – Other support duplicating research or budgetary items already funded by an NIH grant. Overlap also occurs when any project-supported personnel has time commitments exceeding 12 person months.

P

Program Announcement Reviewed in an Institute (PAR) – Program Announcement with special receipt, referral and/or review considerations.

Parent Announcement – NIH-wide funding opportunity announcement enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism [e.g., Research Project Grant (Parent R01)].

Payback – Time and effort fellows and T32 trainees must repay the Government. During the first year, trainees owe one month of payback for every month of support; then they start paying back one month for every month worked.

Payline – A percentile-based funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications coming to an NIH Institute with the amount of funds available.

Peer Review – A system for evaluating research applications using reviewers who are the professional equals of the applicant.

Percentile – Represents the relative position or rank of each priority score (along a 100.0 percentile band) among the scores assigned by a particular study section.

Person Months – Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort.

Pre-application – A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.

President's Budget – The annual budget request submitted to Congress by the U.S. President. The process begins with a budget request from the IC, which, as part of the entire NIH budget request, is modified by the Office of Management and Budget.

Principal Investigator – An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity. Also known as Program Director or Project Director.

Prior Approval – Written approval from the designated Grants Management Officer (GMO) required for specified post award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds.

Priority score – A numerical rating that reflects the scientific merit of the proposed research relative to stated evaluation criteria.

Privacy Act – A law protecting against needless collection or release of personal data. Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Program - A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs carrying out their missions through the award of grants or cooperative agreements to other organizations.

Program Announcement (PA) – An announcement by an NIH Institute or Center requesting applications in the stated scientific areas. Program Announcements (PA) are published in the NIH Guide for Grants and Contracts.

Program Balance – The need to balance an Institute's support of research in all its programmatic areas with its high-quality applications eligible for funding.

Program Classification Code (PCC) – An internal code unique for each I/C indicating the I/C's scientific interest and used to identify internal programs, branch classifications, the science or disease area, and sometimes program officials.

Program Official (PO) – The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

Programmatic Reduction – The dollar amount a grant award is reduced from the amount recommended by the study section (scientific review group). This is done so Institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Progress Number – Commonly referred to as the application number or grant number, depending upon its processing status. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code.

Project Period – The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and non-competing extensions.

Protocol – Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

Public Access Policy – The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states: *The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication:* Provided, *That the NIH shall implement the public access policy in a manner consistent with copyright law.*

PubMed – Provides access to citations from biomedical literature. It includes over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s, along with links to full text articles and other scientific resources. These citations are indexed with a PMID, a series of numbers.

R

Rating Criteria – *See* Initial Peer Review Criteria.

Real Property – Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.

Rebuttal – Procedure for contesting the peer review of a grant application. Synonymous with appeal.

Receipt, Referral, and Assignment of Applications – Routing of applications arriving at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an Institute and refer it to a scientific review group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self assign.

Recipient – Organizational entity or individual receiving a grant or cooperative agreement. *See* Grantee.

Recommended – Designation given by a study section advising funding of an application. The application gets a priority score and summary statement. Roughly the top half of applications being reviewed are recommended for funding.

Recommended Levels of Future Support – Funding level recommended for each future year approved by the scientific review group, subject to availability of funds and scientific progress.

Re-Competing – Grant whose term (e.g., 4 years) is over and for which the applicant is again seeking NIH support. Also known as type 2, competing continuation application, and renewal.

Request for Application (RFA) – The official statement inviting grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.

Request for Proposals (RFP) – Announces that NIH would like to award a contract to meet a specific need, such as the development of an animal model. RFPs have a single application receipt date and are published in the NIH Guide for Grants and Contracts.

Research – A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed “research and development.”

Research Grants – Extramural awards made for Other Research Grants, Research Centers, Research Projects, and SBIR/STTRs. Includes the following: R,P,M,S,K,U series (excluding UC6) DP1, DP2, D42, G12.

Research Misconduct – Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Research Portfolio – The cohort of grants supported by a given NIH organization.

Research Projects – Includes the following selected Research Grant and Cooperative Agreement activities: R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, P01, P42, PN1, U01, U19, UC1, NIGMS P41.

Research Project Grant (RPG) – Supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies. *See* Research Projects.

Research Supplement – Monies adding funds to an existing grant to support and promote diversity, people with disabilities, and people returning to work from family responsibilities.

Restriction – Special term and condition in a Notice of Award or article in a contract that limits activities and expenditures for human subjects or animal research. It may be lifted or adjusted after the award if the requirements are met.

Resubmission – Grants.gov term for a grant application resubmitted to NIH after a PD/PI applicant who did not succeed in getting funded revises it based on feedback from the initial peer review. Previous NIH term was "revision." A resubmission has an entry in its application identification number (e.g., A1).

Review Cycle – Refers to the Center for Scientific Review's thrice yearly initial peer review cycle, from the receipt of applications to the date of the review.

Revision – Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review. The NIH term has been "competing supplemental." NOTE: The former NIH term, "revision," is now “resubmission” in Grants.gov.

S

Salary Cap/Limitation – A legislatively mandated provision limiting the direct salary (also known as salary or institutional base salary, but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts.

Scientific Overlap – Overlap of support occurs when substantially similar research is proposed in more than one concurrent PHS grant application.

Scientific Review Officer (SRO) – Federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.

Scientific Review Group (SRG) – The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award. Also known as Study Section.

Scored – In the peer review process, applications judged by a study section to be competitive (i.e., generally in the upper half of the applications reviewed). These applications are assigned a priority score and forwarded to the appropriate Institute/Center for the second level of review.

Selective Pay – The funding of a small number of programmatically important applications at the margin of the payline as recommended by Council.

Set-Aside – Money taken out of the budget for a specific purpose, for example, to fund a congressionally mandated program.

Sex as a Biological Variable (SABV) – NIH expects that sex as a biological variable will be factored into research designs, analyses and reporting in vertebrae animals and human studies. See: Consideration of Sex as a Biological Variable in NIH-funded Research: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html

Signing Official (SO) – Person with has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The SO can register the institution, and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information.

An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Small Business Concern – A business independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 Code of Federal Regulations (CFR) Part 121.

Small Business Innovation Research (SBIR) – A program designed to support small business concerns conducting innovative research/research & development with potential for commercialization. For the computation of success rates, SBIR awards are not included in the count of RPGs.

Small Business Technology Transfer (STTR) – A program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution. For the computation of success rates, STTR awards are not included in the count of RPGs.

Special Council Review (SCR) – Advisory Council members provide additional consideration of new and renewal applications from well-supported investigators who currently receive $1 million or more in direct costs of NIH funding for RPGs. See: Notice of NIH Special Council Review of Research Applications from PDs/PIs with More than $1.0 Million Direct Costs in Annual NIH Support: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html

Special Emphasis – The NIDDK's policy to set aside funds that are used by the respective program divisions to fund meritorious grants whose competitive position places them beyond the established regular payline. It is the responsibility of the respective program divisions to identify such grants and through its established review procedures to determine which grants meet the Special Emphasis (SE) criteria and receive Subcouncil endorsement for funding. Each such application is then nominated for the Division Director's concurrence and approval by the Institute Director.

Specific Aims – A component of an application's Research Plan which describes concisely and realistically what the proposed research or activity intends to accomplish by the end of the grant. Includes broad, long-term goals; hypothesis or hypotheses to be tested; and specific time-phased research objectives (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology).

Statement of Work (SOW) – In a contract proposal, the detailed description of the work to be performed under the contract.

Streamlined Non-Competing Award Process (SNAP) – Simplified process for the submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period. All NIH award notices identify whether the grant is subject to or excluded from SNAP.

Streamlined Review (formerly Triage) – In the CSR peer review process, applications judged by a study section to be in the lower half of the applications evaluated in a given review round. These

applications are generally not discussed during the study section meeting, but returned to the applicant with the assigned reviewers' written comments with no priority score. *See* Unscored.

Study Section – Panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Also called scientific review group (SRG) or initial review group (IRG).

Subaward – Collaborative arrangement in support of a research project in which part of an activity is carried out through a formal agreement between a grantee and one or more other organizations. Also known as consortium agreement.

Success Rate – Indicates the percentage of reviewed RPG applications receiving funding computed on a fiscal year basis. It is determined by dividing the number of competing applications funded by the sum of the total number of competing applications reviewed and the number of funded carryovers. NOTE: Applications having one or more amendments in the same fiscal year are only counted once. Success rate computations exclude SBIR/STTRs.

Success Rate Base – The basis for computing the Research Project Grant (RPG) success rate. It includes the total number of competing applications reviewed (the number of applications subjected to a streamlined review process). Also known as Rate Base.

Summary Statement – A combination of the reviewers' written comments and the Scientific Review Administrator's (SRA's) summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Supplement – A request for additional funds either for the current operating year or for any future year recommended previously. Also known as a Type 3 application or award, a supplement can be either non-competing (administrative) or competing (subject to peer review).

T

Targeted Research – Research funded as a result of an Institute set-aside of dollars for a specific scientific area. Institutes solicit applications using research initiatives (RFAs for grants, RFPs for contracts). Targeted research applications are reviewed by chartered peer review committees within Institutes. The opposite is Investigator-Initiated Research.

Technology Transfer – Sharing of knowledge and facilities among Federal laboratories, industry, universities, Government, and others to make federally generated scientific and technological advances accessible to private industry and State and local governments.

Terms and Conditions of Award – All legal requirements imposed on a grant by NIH, whether based on statue, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The Notice of Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Tethered Application/Grant – When applications are submitted for multiple PI's from multiple organizations, the application from the partnering Institutions are associated and reviewed as a single project. If an award is made, each of the involved institutions will receive a separate grant to fund the

collaborative project. All applications are linked by a common project title and by cross-references within each application.

Total Project Costs – The total allowable costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

Training Awards – Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as help professional schools to establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F).

Translational Research – Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Triage – *See* Streamlined Review

Type – *See* Application Types.

U

Underrepresented Group – Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders. Used as an eligibility requirement for diversity supplements, fellowships (F31), and other NIH programs.

Unscored – In the Center for Scientific Review peer review process, applications judged by a study section to be noncompetitive are generally in the lower half of the applications to be reviewed. These applications are not given a priority score, although they are reviewed and applicants receive a summary statement. Between FY 1992 and FY 1995 the term "Not Recommended for Further Consideration" (NRFC) referred to noncompetitive applications.

V

Validation – The systematic check of applications against the NIH application guide and Funding Opportunity Announcement instructions. The process can generate errors or warnings.

W

Withholding of Support – A decision by NIH not to make a non-competing continuation award within the current competitive segment.

Book of NIH Abbreviations and Acronyms

Letter Codes Designating Funding for NIH Institutes, Centers in Grant Applications

Abbreviation	NIH Institutes, Centers	Letter Code Designating Funding Institute In Grant Applications
CC	Clinical Center*****	
CIT	Center for Information Technology*	
CSR	Center for Scientific Review*	
FIC	John E. Fogarty International Center	**TW**
NCATS	National Center for Advancing Translational Sciences	**TR**
NCCIH	National Center for Complementary and Integrative Health	**AT**
NCI	National Cancer Institute	**CA**
NEI	National Eye Institute	**EY**
NHGRI	National Human Genome Research Institute	**HG**
NHLBI	National Heart, Lung, and Blood Institute	**HL**
NIA	National Institute on Aging	**AG**
NIAAA	National Institute on Alcohol Abuse and Alcoholism	**AA**
NIAID	National Institute of Allergy and Infectious Diseases	**AI**
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	**AR**
NIBIB	National Institute of Biomedical Imaging and Bioengineering	**EB**

*** Does Not Make Extramural Awards**

Abbreviation	NIH Institutes, Centers, Offices	Letter Code Designating Funding Institute In Grant Applications
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development	**HD**
NIDA	National Institute on Drug Abuse	**DA**
NIDCD	National Institute on Deafness and Other Communication Disorders	**DC**
NIDCR	National Institute of Dental and Craniofacial Research	**DE**
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	**DK**
NIEHS	National Institute of Environmental Health Sciences	**ES**
NIGMS	National Institute of General Medical Sciences	**GM**
NIH	National Institutes of Health	
NIMH	National Institute of Mental Health	**MH**
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)	**MD**
NINDS	National Institute of Neurological Disorders and Stroke	**NS**
NINR	National Institute of Nursing Research	**NR**
NLM	National Library of Medicine	**LM**
OD	Office of the Director	**OD**

Acronym	Definition
A	
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
AALAS	American Association for Laboratory Animal Science
AAMC	Association of American Medical Colleges
AAP	American Academy of Pediatrics
AAPHP	American Academy of Pediatrics
ABL	Applied BioScience Laboratories for Acquired Immunodeficiency Syndrome
ABRCMS	Annual Biomedical Research Conference for Minority Students
ABSL	American Bio-Safety Level
ACD	Advisory Committee to the Director
ACEP	American College of Emergency Physicians
ACF	Administration for Children and Families (DHHS)
ACGME	Accreditation Council for Graduate Medical Education
ACPM	American College of Preventive Medicine
ACR	American College of Radiology
ACS	American Cancer Society
ACS	American College of Surgeons
ACSI	American Customer Satisfaction Index
ACSR	AIDS and Cancer Specimen Resource, NCI
ACTG	AIDS Clinical Trials Group
ACTIS	AIDS Clinical Trials Information Service
ACTU	AIDS Clinical Trials Unit
ACUC	Animal Care and Use Committee
ADAMHA	Alcohol Drug Abuse and Mental Health Administration (now **SAMSHA**)

ADB	Automated Data Base System
ADB	Administrative Database System (NIH)
ADC	AIDS Dementia Complex
ADCR	Associate Director for Clinical Research
ADD	Attention Deficit Disorder
AdEERS	Adverse Event Expedited Reporting System
ADP	Automated Data Processing
ADR	Adverse Drug Reactions
ADR	Alternative Dispute Resolution
AE	Adverse Event
AER	Adverse Event Reporting
AFGE	American Federation of Government Employees
AFIP	Armed Forces Institute of Pathology
AFIP	Animal Facilities Improvement Program
AFL/CIO	American Federation of Labor/Congress of Industrial Organizations
AGEMAP	Atlas of Gene Expressions in Mouse Aging Project
AGRICOLA	AGRICultural OnLine Access
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AI	Amelogenesis Imperfecta
AI/ANO	American Indian/Alaskan Native Organization
AID	U.S. Agency for International Development
AIDS	Acquired Immunodeficiency Syndrome
AIDSinfo	HHS AIDS information Web site
AIEDRP	Acute Infection and Early Disease Research Program

AIRO	Agency Intramural Research Integrity Officer
AIRO	American Indian Research Opportunities
AITRC	Allergy, Immunology, and Transplantation Research Committee
AITRP	AIDS International Training and Research Program, FIC
AJCC	American Joint Committee on Cancer
AL	Annual Leave
ALAT	Assistant Laboratory Animal Technician (Certified by AALAS)
ALERT system	HHS system for disseminating information to Public Health Service officials about organizations or people charged with or found to have engaged in scientific misconduct (PHS)
AMA	American Medical Association
AMB	AIDS Malignancy Bank
AMC	AIDS Malignancy Consortium
AMC	Acquisition Management Committee
AMD	Age-related Macular Degeneration
AMHPS	Association of Minority Health Professionals Schools
AMIA	American Medical Informatics Association
AMLCD	Active matrix liquid crystal display
AMSSC	Administrative Management Systems Steering Committee
AMWG	AIDS Malignancies Work Group
ANL	Argonne National Laboratory, Argonne, IL
ANPR	Advance Notice of Proposed Rulemaking
ANSI	American National Standards Institute
AO	Administrative Official/ Administrative Office/ Administrative Officer
AOA	Administration on Aging
AP	Acquisition Plan
APA	Administrative Program Assistant

APAC	Annual Payback Activities Certification
APAO	Asian and Pacific Islander American Organization
APC	NIH Purchase Card Program Agency Program Coordinator
APD	Animal Program Director
APHA	American Public Health Association
APHIS	USDA - Animal and Plant Health Inspection Service
API	Application Programming Interfaces
APN	Advanced Practice Nursing
ARA	Awaiting Receipt of Application
ARAC	Administrative Restructuring Advisory Committee/Work Group on Acquisition
ARAC	AIDS Research Advisory Committee (NIAID)
ARB	Architecture Review Board
ARC	Administrative Resource Center
AREA	NIH Academic Research Enhancement Award (R15)
ARL	U.S. Army Research Laboratory
ARND	Alcohol-related Neurodevelopmental Disorder
ARRA	American Recovery and Reinvestment Act of 2009
ARRR	AIDS-Related Research Review
ARS	Agriculture Research Service
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASAP	As Soon As Possible
ASB	Administrative Services Branch
ASBTF	Assistant Secretary for Budget, Technology and Finance
ASDC	Administrative Skills Development Curriculum

ASH	Assistant Secretary for Health, PHS
ASI	Addiction Severity Index
ASP	Animal Study Proposal
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPER	Assistant Secretary for Personnel Administration, DHHS
ASPH	Association of Schools of Public Health
ASTHO	Association of State and Territorial Health Officials
AT	Administrative Technician
ATCC	American Type Culture Collection, Manassas, VA
ATI	Analytic Treatment Interruption
ATIS	AIDS Treatment Information Service
ATPM	Association of Teachers and Preventive Medicine
ATSDR	Agency for Toxic Substances and Disease Registry
AVEG	AIDS Vaccine Evaluation Group
AVEU	AIDS Vaccine Evaluation Unit
AVRC	AIDS Vaccine Research Committee
AWA	Animal Welfare Act
AWOL	Absence Without Official Leave
AWS	AIDS-associated Wasting Syndrome
AZT	Zidovudine (generic name) or Azidothymidine

B

B&F	Buildings and Facilities
B&P	Bid and Proposal
B/Start	Behavioral Science Track Award for Rapid Transition

BAA	Broad Agency Announcement
BAFO	Best and Final Offer
BARC	Beltsville Agricultural Research Center
BBBP	Biobehavioral and Behavioral Processes
BC	Biomarker Consortium
BC/BS	Blue Cross/Blue Shield
BCP	Best Community Practice and Biophysical and Chemical Sciences
BCS	Biochemical Sciences
BDCN	Brain Disorders and Clinical Neuroscience
BDP	Biopharmaceutical Development Program
BDR	Budget Data Request
BEA	Bureau of Economic Analysis
BECON	Bioengineering Consortium (NIH OD)
BEMIS	Biomaterials and Medical Implant Science
BEP	Bureau of Engraving and Printing
BESA	Border Epidemiologic Study of Aging
BEST	Biomonitoring of Environmental Status and Trends
BFRL	Building and Fire Research Laboratory
BGCRG	Breast and Gynecologic Cancer Research Group
BHPr	Bureau of Health Professions
BIA	Bureau of Indian Affairs
BIC	Business Information Center
BIG	Blacks in government
BIGR	Biomaterials and Information for Genomic Research™ (Ardais Corporation)
BIMAS	Bioinformatics Molecular Analysis Section

BIO	Biotechnology Industry Organization
BIRADS	Breast Imaging Reporting and Data System
BIRN	Biomedical Informatics Research Network
BIS	Bureau of Industry and Security
BISM	Blind Industries and Services of Maryland
BISTI	Biomedical Information Science and Technology Initiative
BISTIC	Bioinformatics Consortium (NIH OD)
BITS	Business Information Technology System
BJA	Bureau of Justice Assistance
BJS	Bureau of Justice Statistics
BL-3	Biosafety Level 3
BLA	Biologics License Application
BLIRC	Biomedical Library and Informatics Review Committee
BLM	Bureau of Land Management
BLS	Board on Life Sciences
BLS	Bureau of Labor Statistics
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BMDO	Ballistic Missile Defense Organization
BML	Biological Material License
BMMR	Biological Models and Materials Research
BMO	Business Management Office
BNA	Bureau of National Affairs
BNL	Brookhaven National Laboratory, Upton, NY (Department of Energy Organization)
BOA	Basic Ordering Agreement
BOG	Board of Governors, NIH

BOP	Federal Bureau of Prisons
BOR	Board of Regents
BOR	Bureau of Reclamation
BoS	Board of Survey
BPA	Blanket Purchase Agreement
BPD	Bureau of Public Debt
BPH	Benign Prostatic Hyperplasia
BPHC	Bureau of Primary Health Care
BPSRG	Basic Prevention Science Research Group
BRB	Benefits Review Board
BRCA	Breast Cancer
BRD	Biological Resource Division,
BRDPI	Biomedical Research and Development Price Index, measures real annual changes in the prices of items and services required for research and development (R&D) activities
BRFSS	Behavioral Risk Factor Surveillance System
BRG	Biometry Research Group
BRIN	Biomedical Research Infrastructure Network
BRMP	Biological Response Modifiers Program
BSA	Board of Scientific Advisors
BSC	Board of Scientific Counselors
BSC	Business Service Centers
BSI	Brief Symptom Inventory
BSL	Bio-Safety Level
BSSC	Behavioral and Social Sciences Coordinating Committee
BTP	Biotechnology Training Program
BTR	Biomedical Technology Resource

BTS	Bureau of Transportation Statistics
BVA	Board of Veterans Appeals

C

CAM	Complementary and Alternative Medicine
CBER	Center for Biologics Evaluation and Research
CBIAC	Chemical and Biological Defense Information Analysis Center
CBO	Congressional Budget Office
CBT	Computer-Based Training
CC	Warren Grant Magnuson Clinical Center, NIH
CCB	Configuration Control Board
CCB	Child Care Bureau
CCC	Commodity Credit Corporation
CCO	Chief Contracting Officer
CCR	Center for Career Resources (OD)
CCR	Center for Cooperative Resolution
CCR	Commission on Civil Rights
CCSS	Childhood Cancer Survivor Study
CCTAT	Cooperative Clinical Trials in Adult Kidney Transplantation
CCTPT	Cooperative Clinical Trials in Pediatric Kidney Transplantation
CDA	Confidential Disclosure Agreement
CDBG	Community Development Block Grants
CDC	Centers for Disease Control and Prevention, PHS (Public Health Service)
CDE	Common Data Element
CDER	Center for Drug Evaluation and Research

CDFI	Community Development Financial Institutions
CDHR	Center for Devices and Radiological Health
CDMC	Central Data Management Center
CDMRP	Congressionally Directed Medical Research Program
cDNA	Complementary DNA
CDs	Communication Directors
CES	Central E-mail Service
CDP	Career Development Plan
CDR	Clinical Drug Request
CDUS	Clinical Data Update System
CDW	Consultant Days Worked
CEA	Council of Economic Advisers
CEC	Contractor Establishment Code
CEDR	Comprehensive Epidemiologic Data Resource
CEGS	Centers of Excellence in Genomic Science
CEL	Commercial Evaluation License
CEN	Bureau of the Census
CEPPO	Chemical Emergency Preparedness and Prevention Office
CEPS	Center for Earth and Planetary Studies
CEQ	Council on Environmental Quality
CERCLIS	Comprehensive Environmental Response, Compensation, & Liability Information System
CETEC	Topographic Engineering Center
CF	Consent Form
CFAR	Centers for AIDS Research
CFC	Combined Federal Campaign

CFDA	Catalog of Federal Domestic Assistance, a database that helps the Federal Government track all programs it has domestically funded. Federal programs are assigned a number in the database called the "CFDA number."
CFO	Chief Financial Office
CFOC	Chief Financial Officers Council
CFR	Code of Federal Regulations
CFS CRC	Chronic Fatigue Syndrome Cooperative Research Centers
CFSAN	National Center for Food Safety and Applied Nutrition
CGAP	Competitive Grant Application Process
CGH	Comparative genomic hybridization
CHAMPVA	Civilian Health and Medical Program of the Department of Veterans Affairs
CHB	Community Health Branch (DOHS)
CHID	Combined Health Information Database
ChiMP	NIH Chimpanzee Management Program
CHIMP	Chimpanzee Health, Improvement, Maintenance and Protection Act
CHTN	Cooperative Human Tissue Network
CIAO	Critical Infrastructure Assurance Office
CIC	Consumer Information Center
CID	Center of Infectious Diseases (CDC)
CIDI	Composite International Diagnostic Interview (Clinical Trials Standard)
CIO	Chief Information Officer
CIPRA	Comprehensive International Program for Research on AIDS
CIS	Cancer Information Service
CISET	Committee on International Sciences, Engineering, and Technology
CIT	Center for Information Technology
CJD	Creutzfeldt-Jakob Disease

CLC	Community Liaison Council
CLIA	Clinical Laboratories Improvement Act
CLM	Council of Logistics Management
CMAB	Complaints Management and Adjudication Branch (OEO)
CMAP	Cancer Molecular Analysis Project
CMB	Comparative Medicine Branch
CMBD	Collection Management & Delivery Branch (DLS)
CME	Continuing Medical Education
CMHS	Center for Mental Health Services
CML	Chronic Myeloid Leukemia
CMO	Committee Management Officer, IC person responsible for the oversight of all NIH Federal advisory committees under the auspices of the Federal Advisory Committee Act; responsible for developing committee charter, preparing nomination and appointment documents for membership to committees, providing technical assistance to committee members, providing initial review of conflict of interest disclosures, etc.
CMP	Contract Management Program
CMP/HMO	Comprehensive Medical Plans/Health Maintenance Organizations
CMPP	Center for Nutrition Policy and Promotion
CMS	Centers for Medicare and Medicaid Services
CMSP	Cooperative Medical Sciences Program
CMV	Center for Minority Veterans
CNCRIT	Collaborative Network for Clinical Research on Immune Tolerance
CNS	Central Nervous System
CO	Contracting Officer
COB	Close of Business
COBRE	Centers of Biomedical Research Excellence
CoC	Commission on Cancer

CoC	Council of Councils
COC	Certificate of Confidentiality
COG	Children's Oncology Group
COGA	Collaborative Study on the Genetics of Alcoholism
COI	Conflict of Interest
COLA	Cost of Living Allowance
CONSER	Cooperative Online Serials
COOG	Continuity of Operations Group
COOP	Continuity of Operations Plan
COP	Continuation of Pay
COP	Costal Ocean Program
COPR	Council of Public Representatives (serves NIH Director)
COPS	Office of Community Oriented Policing Services
COPTRG	Community Oncology and Prevention Trials
COR	Career Opportunities in Research Education and Training
COSEPUP	Committee on Science Engineering and Public Policy
COTA	Career Opportunities Training Agreement (HHS)
COTS	Commercial Off-The-Shelf Software Products
CPA	Cooperative Project Assurance
CPAF	Cost Plus Award Fee
CPDF	Central Personnel Data File
CPE	Continuing Professional Education
CPFP	Cancer Prevention Fellowship Program
CPI	Consumer Price Index
CPIF	Cost Plus Incentive Fee

CPMS	Defense Civilian Personnel Management Service
CPO	Corrections Program Office
CPS	Contractor Performance System
CPS	Center for Prevention Services (CDC)
CPSC	Consumer Product Safety Commission
CR	Continuing Resolution
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement
CRC	Cooperative Research Center
CRC	Civil Rights Center
CRC	New Clinical Research Center
CRF	Case Report Form (Source Document for Clinical Studies)
CRIB	Central Institutional review Board
CRIC	Chronic Renal Insufficiency Cohort
CRIS	Clinical Research Information System
CRISP	Computer Retrieval of Information on Scientific Programs, A searchable biomedical database of federally supported proposed research conducted at universities, hospitals, institutions, etc.
CRL	Charles River Laboratories
CRM	Customer Relations Manager
CRO	Contract Research Organization
CRP	Conference Room Pilot
CRP	Conservation Reserve Program
CRS	Congressional Research Service
CRS	Clinical Research Scholar
CRS	Community Relations Service
CRTA	Cancer Research Training Award

CRTP	Clinical Research Training Program
CRVP	Clinical Research Volunteer Program
CS	Contract Specialist
CSAC	Central Services Advisory Committee
CSAP	Center for Substance Abuse Prevention
CSAT	Center for Substance Abuse Treatment
CSB	Customer Service Branch (DMAPS)
CSB	Chemical Safety and Hazard Investigation Board
CSD	Client Services Division
CSE	Office of Child Support Enforcement
CSI	Center for the Study of Intelligence
CSR	Center for Scientific Review
CSREES	Cooperative State Research, Education, and Extension Service
CT	Computed Tomography
CTA	Clinical Trial Agreement
CTAG	Clinical Translation Advisory Group
CTC	Common Toxicity Criteria
CTEP	Clinical Therapeutic Evaluation Program
CTEP	Cancer Therapy Evaluation Program
CTN	National Drug Abuse Treatment Clinical Trials Network
CTP	Community Treatment Program
CTSA	Clinical and Translational Science Awards
CTSU	Clinical Trials Support Unit
CU	Coordinating Unit
CUAP	College and University Affiliations Program

Cumulus SPMS	Cumulus Slide/Presentation Management System
CVS	Cardiovascular Sciences
CVS	Chorionic Villus Sampling
CWC	Chemical Weapons Convention
CWD	Chronic Wasting Disease
CY	Calendar Year

D

D&A	Design and Analysis Workgroup
D&B	Dun & Bradstreet Number
DAP	Division of Acquisition Programs, OLAO
DARPA	Defense Advanced Research Projects Agency
DASAM	Deputy Secretary for Administration and Management
DASPA	Division of Advanced Studies and Policy Analysis
DB	Design Branch (DMAPS)
DBASSE	Division of Behavioral and Social Sciences and Education
DBBD	Division of Biological Basis of Disease
DBDR	Division of Blood Diseases and Resources
DBPS	Division of Bioengineering and Physical Science
DBT	Division of Biomedical Technology
DCA	Division of Cost Allocation
DCAA	Defense Contract Audit Agency
DCCT	Diabetes Control and Complications Trial
DCIS	Department Contract Information System
DCLG	Director’s Consumer Liaison Group

DCM	Division of Comparative Medicine
DCMC	Defense Contract Management Command
DCMS	Division of Mail and Courier Services (ORS)
DCPS	Division of Clinical and Population Based Studies
DCR	Division of Career Resources, OHRM, NIH
DCR	Division of Clinical Research
DCRT	Division of Computer Research and Technology (now CIT)
DDC	Defense Distribution Center
DDER	Deputy Director of Extramural Research, NIH
DDIR	Deputy Director for Intramural Research
DDKR	Drug Delivery & Kinetics Resource (DBPS)
DDM	Deputy Director for Management
DDN	Division of Digestive Diseases and Nutrition, NIDDK
DDP	Diamminedichloroplatinum
DEA	Division of Extramural Activities, NIDDK
DEC	Deputy Ethics Counselor
DeCA	Defense Commissary Agency
DEIS	Division of Extramural Information Systems
DELPRO	Delegated Procurement System
DEM	Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
DEMS	Division of Events Management Services (PES or P&ES)
DEPC	Division of Emergency Preparedness & Coordination
DEPS	Division of Epidemiology and Population Studies
DERT	Division of Extramural Research and Training
DES	Division of Engineering Services

DFAS	Defense Finance and Accounting Service (sends out DHHS/NIH W2s for honorariums, etc.)
DFM	Division of Financial Management
DHHS	Department of Health and Human Services
DHRS	Division of Human Resource Systems, OHRM, NIH
DHVD	Division of Heart and Vascular Diseases
DICOM	Digital Imaging and Communications in Medicine
DINFOS	Defense Information School
DIR	Division of Intramural Research, NIDDK
DITA	Division of Information Technology Acquisition, OLAO (also known as NITAAC)
DITR	Division of International Training and Research
DLD	Division of Lung Diseases
DLS	Division of Library Services
DLS	Division of Logistics Services, OLAO
DLT	Digital linear tape
DM	Data management
DMAPS	Division of Medical Arts and Printing Services
DMAS	Data Management and Analysis Subcommittee
DMCM	Division of Molecular and Cellular Mechanisms
DMCS	Division of Mail and Courier Services
DMDC	Defense Manpower Data Center
DMID	Division of Microbiology and Infectious Diseases
DMS	Division of Management Services
DNA	Deoxyribonucleic Acid
DOHS	Division of Occupational Health and Safety
DORRA	DLA Office of Operations Research and Resource Analysis

DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DPPS	Division of Personal Property Services, OLAO
DPS	Division of Physiological Systems
DPSM	Division of Physical Security Management
DRA	Division of Research Acquisition, OLAO
DRI	Division of Research Infrastructure
DRR	Division of Receipt and Referral
DRS	Division of Radiation Safety
DRSB	Diagnostic & Research Services Branch
DS	Division of Safety, Office of Research Services
DSEIS	Division of Scientific Equipment and Instrumentation Services (ORS)
DSFM	Division of Space and Facility Management
DSMB	Data and Safety Monitoring Board
DSM-IV	Diagnostic & Statistical Manual of Mental Disorders – 4th Edition
DSO	Division of Security Operations
DSS	Division of Support Services
DSSA	Division of Station Support Acquisition, OLAO
DTIC	Defense Technical Information Center
DTM	Department of Transfusion Medicine (ORS)
DTP	Developmental Therapeutics Program
DTTS	Division of Travel and Transportation Services
DUNS	Data Universal Numbering System
DVR	Division of Veterinary Resources
DW	Data Warehouse
DWD	Division of Workforce Development

E

EA	Expanded Authorities
EA	Enterprise Architecture
EAC	External Advisory Committee
EACC	External Affairs Coordinating committee
EAP	Employee Assistance Program
EBSA	Employee Benefits Security Administration
EC	Executive Committee
EC	European Commission
ECA	Executive Committee for Acquisition
ECA	Bureau of Educational and Cultural Affairs
ECAB	Employees' Compensation Appeals Board
ECB	Electronic Council Book
ECFMG	Educational Commission for Foreign Medical School Graduates
ECIE	Executive council on Integrity and Efficiency
ECL	Executive Committee on Logistics
ECOSOC	Economic and Social Council
ECP	Emergency Conservation Program
ECR-LRP	Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds
EDGAR	Electronic Data Gathering, Analysis, and Retrieval
EDI	Electronic Data Interchange
EDIC	Epidemiologic Cohort Study
Edison	Extramural Invention Information Management System
EDRG	Early Detection Research Group

EDRN	Early Detection Research Network
EEO	Equal Employment Opportunity
EEOC	Equal Employment Opportunity Commission
EES	Enterprise E-Mail System
EHP	Environmental Health Perspectives
EHRP	Enterprise Human resources and Payroll System
EIA	Energy Information Administration
EIN	Entity Identification Number
EIR	Employee Invention Report
EIS	Epidemic Intelligence Service
ELS	Earnings and Leave Statement
ELSI	Ethical, Legal and Societal Implications
EL-TRAINS	Electronic Logistics Training & Support Network
EM	Office of Environmental Management
EML	Environmental Measurement Laboratory
EMPSB	Events Management Program Support Branch (DEMS)
ENC	Eisenhower National Clearinghouse
ENR	Endocrinology and Reproductive Sciences
ENS	Early Notification System
EO	Executive Order
EOB	Editorial Operations Branch
EOC	Ethics Oversight Committee
EOD	Entrance on Duty
EOIR	Executive Office for Immigration Review
EOP	Executive Office of the President

EOUSA	Executive Office for United States Attorneys
EP	Extramural Programs
EPMC	Extramural Program Management Committee
EPN	Executive Plaza North (6130 Executive Blvd.; Rockville, MD 20852)
EPRU	Enteric Pathogens research Unit
EPS	Executive Plaza South (6120 Executive Blvd.; Rockville, MD, 20852)
EPSCoR	Experimental Program to Stimulate Competitive Research
EPSS	Electronic Performance Support Systems
eRA	Electronic Research Administration; responsible for IMPAC II
ERDA	Energy Research and Development Administration
EREN	Energy Efficiency and Renewable Energy Network
ERIC	Educational Resources Information Center
EROD	Educational Resource Organizations Directory
ERP	Extramural Research Program
ERS	Economic Research Service
ERSB	Equipment Rental & Sakes Branch (DSEIS)
ES	Executive Secretariat (NIH)
ESA	Extramural Scientist Administrator
ESA	Employment Standards Administration
ESA	Economics and Statistics Administration
ESDIM	Environmental Services Data and Information Management
ESG	Executive Staffing Group (REPS, PMB, NCI)
eSNAP	Electronic Streamlined Non-competing Award Process
ETA	Employment and Training Administration
ETSO	Employee Transportation Services Office

F

F & A	Facilities and Administrative Cost
F Awards	Fellowship Awards
FACA	Federal Advisory Committee Act
FAES	Foundation for Advanced Education in the Sciences
FAI	Fair Act Inventory
FAIR Act	Federal Activities Inventory Reform Act
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FARB	Funding Advisory Review Board
FASAB	Federal Accounting Standards Advisory Board
FASEB	Federation of American Societies for Experimental Biology
FCC	Federal Communications Commission
FCOI	Financial Conflict of Interest
FCRDC	Frederick Cancer Research and Development Center
FDA	Food and Drug Administration (PHS)
FDP	Federal Demonstration Partnership
FECA	Federal Employees' Compensation Act
FEGLI	Federal Employees' Group Life Insurance
FEHBP	Federal Employees' Health Benefit Program
FEMA	Federal Emergency Management Agency
FERC	Federal Energy Regulatory Commission
FERS	Federal Employees' Retirement System
FFLA	Family Friendly Leave Act
FIC	John E. Fogarty International Center

FICA	Federal Insurance Contributions Act (Social Security)
FIRST	First Independent Research Support and Transition Award
fMRI	Functional Magnetic Resonance Imaging
FMS	Financial Management Service
FNIH	Foundation for the National Institutes of Health
FOIA	Freedom of Information Act of 1966, amended 1986
FRB	Federal Reserve Board
FRS	Federal Reserve System
FTC	Federal Trade Commission
FTE	Full Time Equivalent
FTTP	Full-Time Training Position
FWA	Federal Wide Assurance
FY	Fiscal Year (October 1 – September 30)
FYI	For Your Information

G

GAO	General Accounting Office, Congress
GBV-C	Hepatitis G (GB Virus-C)
GCRC	General Clinical Research Center
GDB	Human Genome Database
GH	Growth Hormone
GM	Grants Management
GMB	Grants Management Branch Office
GME	Graduate Medical Education
GMO	Grants Management Officer

GMS	Grants Management Specialist
GPA	Grade Point Average
GPEA	Government Paperwork Elimination Act of 1998
GPO	Government Printing Office
GPRA	Government Performance Results Act of 1993
GPS	Global Positioning Satellite System
GRE	Graduate Record Examinations
GS	General Schedule
GSA	General Services Administration
GTA	Grants Technical Assistant
GWAC	Government-Wide Acquisition Contract

H

HAART	Highly Active Antiretroviral Therapy
HBCU	Historically Black Colleges and Universities
HBV	Hepatitis B Virus
HCV	Hepatitis C virus
HDR-LRP	Loan Repayment Program for Health Disparities Research
HEM	Hematology Study Section
hESC	Human Embryonic Stem Cells
HHMI	Howard Hughes Medical Institute
HHS	Health and Human Services (Department of)
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization

HPV	Human Papillomavirus
HQ	Headquarters
HRSA	Health Resources and Services Administration, PHS
HRT	Hormone Replacement Therapy
HSA	Health Scientist Administrator
HSRAC	Human Subjects Research Advisory Committee
HSRB	Human Subjects Review Board
HSV	Herpes Simplex Virus
HTML	Hypertext Markup Language

I

IACUC	Institutional Animal Care and Use Committee
IAG	Interagency Agreement
IAR	Internet Assisted Review
IBC	Institutional Biosafety Committee
IC	Institute and Center (NIH)
ICC	Interstate Commerce Commission
ICD	Institutes/Centers/Divisions
ICF	Informed Consent Form
ID	Identification
IDE	Investigational Device Exemption (FDA)
IDeA	Institutional Development Award Program (NCRR)
IDIQ	Indefinite Delivery Indefinite Quality Contract
IDM	Infectious Diseases and Microbiology
iEdison	NIH's Extramural Electronic Invention Reporting system

IFCN	Integrative, Functional and Cognitive Neuroscience
IG	Inspector General
IHS	Indian Health Service, PHS
IMA	Internal Monitoring Board
IMAGE	Integrated Molecular Analysis of Genomes and their Expression
IMF	International Monetary Fund
IMPAC	Integrated Management, Planning, Analysis and Coordination (Data System)
IMPAC II	Information for Management, Planning, Analysis, and Coordination (grants data system)
IMS/ADB	Information Management System/Administrative Data Base System (DELPRO)
IND	Investigational New Drug Application (FDA)
INS	Immigration and Naturalization Service (now the United States Citizenship and Immigration Services)
IO	Information Officer
IOM	Institute of Medicine, NAS
IP	Intellectual Property
IPC	Incidental Patient Contact
IPF	Institutional Profile File Number
IRA	Individual Retirement Account
IRACDA	Institutional Research and Academic Career Development Award
IRB	Institutional Review Board
IRG	Integrated Review Group, a cluster of study sections responsible for review of grant applications in scientifically related areas; sections share common intellectual and human resources.
IRM	Information Resources Management
IRP	NIH Intramural Research Program
IRPG	Interactive Research Project Grant
IRTA	Intramural Research Training Award or Agreement

ISO	International Organization for Standardization
ISSO	Information Systems Security Office
IT	Information Technology
ITAS	Integrated Time and Attendance System
ITB	Information Technology Branch
ITC	United States International Trade Commission

J

JAX	The Jackson Laboratory
JHU	Johns Hopkins University
JOFOC	Justification for Other than Full and Open Competition
Just-in-time	Grant application timeframe that requires applicants to send some information to NIH only if an award is likely. Also used for other support information, and other items, including: certification of IRB approval, Federal wide assurance, IACU certification, and letter stating key personnel have been trained in protecting human subjects

K

K Awards	Mentored and Career Development Awards
KSA	Knowledge, Skills and Ability Form
KSASF	Knowledges, Skills, Abilities Supplemental Form (NIH-2252-3)
KUH	Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

L

LABS	Laboratory Automated Bibliographic System
LAN	Local Area Network
LAO	Leave Approving Official

LAS	Laboratory Animal Sciences
LAT	Laboratory Animal Technician (AALAS Certified)
LATG	Laboratory Animal Technologist (AAALAS Certified)
LCM	Laser Capture Microdissection
LI	Lead Investigator
LOC	Library of Congress
LOCIS	Library of Congress Information System
LOE	Level of Effort
LOI	Letter of Intent
LRP	Loan Repayment Program (NIH)
LWOP	Leave Without Pay

M

MA	Master Agreement
MAC	Multiple Award Contract
MACs	Multiple Agency Contracts
MARC	Minority Access to Research Career Program
MBRS	Minority Biomedical Research Support
MC	Manual Chapter
MCDN	Molecular, Cellular and Developmental Neuroscience
MCP	NIH Management Cadre Program
MCR	Management Control Review
MCSB	Mail Customer Service Branch (DMCS)
MCRU	Metabolic Clinical Research Unit (in NIH Clinical Center)
MEDLINE/ PUBMED	National Library of Medicine's Database for Scientific Publications

MEO	Most Efficient Organization
MERIT	Method to Extend Research in Time Award
MeSH	Medical Subject Headings
MF	NIH Management Fund
MHC	Major Histocompatibility Complex
MHPF	Minority Health Professionals Foundation
MI	Minority Institutions
MIGA	Multilateral Investment Guarantee Agency
MIS	Medical Information System
ML	Military Leave
MM	Medical Monitor
MODY	Maturity Onset Diabetes of the Young
MORE	Minority Opportunities in Research
MOU	Memorandum of Understanding
MOU/MOA	Memorandum of Understanding/Memorandum of Agreement
MPA	Multiple Project Assurance
MPP	Merit Program Plan (NIH)
MPW	Medical Pathological Waste
MRA	Minimum Retirement Age
MRC	Medical Research Council (UK)
MRI	Magnetic Resonance Imaging
M-RISP	Minority-Research Infrastructure Support Program
mRNA	Messenger RNA
MRS	Magnetic Resonance Spectroscopy
MSDS	Material Safety Data Sheet

MSPB	Merit Systems Protection Board
MTA	Material Transfer Agreement
MTCT	Mother-to-Child Transmission

N

N/A	Not Applicable/Not Available
NAFTA	North American Free Trade Agreement
NAHFE	National Association of Hispanic Federal Executives
NARA	National Archives and Records Administration
NARCH	Native American Research Centers for Health
NARFE	National Association of Retired Federal employees
NAS	National Academy of Sciences (U.S.)
NBAC	National Bioethics Advisory Commission
NBII	National Biological Information Infrastructure
NBN	National Biospecimen Network
NBRSS	NIH Business and Research Support System
NBS	New Business Systems/NIH Business System
NCATS	National Center for Advancing Translational Sciences
NCBI	National Center for Biotechnology Information
NCC	National Coordinating Center for Telecommunications
NCCIH	National Center for Complementary and Integrative Health (NIH)
NCCDPHP	National Center for Chronic Disease and Prevention Health Promotion (CDC)
NCCIC	National Child Care Information Center
NCCLS	National Committee for Clinical Laboratory Standards
NCD	National Council on Disability

NCEH	National Center for Environmental Health (CDC)
NCES	National Center for Education Statistics
NCHS	National Center for Health Statistics
NCI	National Cancer Institute (NIH)
NCICAS	National Cooperative Inner-City Asthma Study
NCIPC	National Center for Injury Prevention and Control (CDC)
NCRR	National Center for Research Resources (dissolved as of December 23, 2011)
NCSDR	National Center on Sleep Disorders Research
NCTR	National Center for Toxicological Research
NCUA	National Credit Union Administration
NCVHS	National Committee on Vital and Health Statistics
NDA	New Drug Application
NDDKDAC	National Diabetes and Digestive and Kidney Diseases Advisory Council
NDIC	National Drug Intelligence Center
NDRI	National Disease Research Interchange
NED	NIH Enterprise Directory
NEI	National Eye Institute (NIH)
NFT	Notification of Foreign Travel
NGA	Notice of Grant Award (also NoGA) [see NOGA p 36/59]
NGO	Non-Government Organization
NHGRI	National Human Genome Research Institute (NIH)
NHIC	National Health Information Center
NHLBI	National Heart, Lung, and Blood Institute (NIH)
NHP	Nonhuman Primate
NHRPAC	National Human Research Protection Advisory Committee

NHSC	National Health Sciences Scholarship
NIA	National Institute on Aging (NIH)
NIAAA	National Institute on Alcohol Abuse and Alcoholism (NIH)
NIAID	National Institute of Allergy and Infectious Disease (NIH)
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Disease (NIH)
NIBIB	National Institute of Biomedical Imaging and Bioengineering (NIH)
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NIH)
NIDA	National Institute on Drug Abuse (NIH)
NIDCD	National Institute on Deafness and Other Communication Disorders (NIH)
NIDCR	National Institute of Dental and Craniofacial Research (NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
NIDRR	National Institute on Disability and Rehabilitation Research
NIEHS	National Institute of Environmental Health Sciences (NIH)
NIGMS	National Institute of General Medical Sciences (NIH)
NIH	National Institutes of Health
NIH DW	NIH Data Warehouse
NIHAC	The National Institutes of Health Animal Center (Poolesville, MD)
NIHITS	NIH Integrated Training System
NIHTC	National Institutes of Health Training Center
NIMH	National Institute of Mental Health (NIH)
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)
NINDS	National Institute of Neurological Disorders and Stroke (NIH)
NINR	National Institute of Nursing Research (NIH)
NIOSH	National Institute for Occupational Safety and Health (CDC)
NIST	National Institute of Standards and Technology

NLAES	National Longitudinal Alcohol Epidemiologic Survey
NLM	National Library of Medicine (NIH)
NLT	Not Later Than
NMA	National Medical Association
NMR	Nuclear Magnetic Resonance
NMS	Nutritional and Metabolic Sciences
NOA	Nature of Action
NOGA	Notice of Grant Award [see NoGA prior page at NGA]
Non-FTE	Non Full-time Equivalent
NOTA	National Organ Transplant Act
NPEBC	National Programs of Excellence in Biomedical Computing
NPRC	National Primate Research Center
NREN	National Research and Education Network
NREVSS	National Respiratory and Enteric Virus Surveillance System
NRFC	Not Recommended for Further Consideration
NRL	Naval Research Laboratory
NRSA	National Research Service Award (e.g., T32, F32)
NS	No Score (lower 50% of grants in study section)
NSF	National Science Foundation
NSRG	Nutritional Science Research Group
NSTC	National Science and Technology Center
NSTL	National Space Technology Laboratories
NTE	Not To Exceed
NTIA	National Telecommunications and Information Administration
NTIS	National Technical Information Service

NTP	National Toxicology Program

O

OA	Office of Administration
OACU	Office of Animal Care and Use
OAM	Office of Administrative Management (OD)
OAMP	Office of Acquisition Management and Policy, OA
OAPP	Office of Adolescent Pregnancy Programs (OASH)
OAR	Office of AIDS Research
OASDI	Old Age Survivor Disability Insurance
OASH	Office of the Assistant Secretary for Health, PHS
OASPA	Office of the Assistant Secretary for Public Affairs
OB	Office of Budget (NIH OD)
OBA	Office of Biotechnology Activities (NIH OD)
OBL	Office of Business Liaison
OBSF	Office of Business Systems & Finance (OD)
OBSSR	Office of Behavioral and Social Sciences Research (NIH OD)
OC	Office of Communications
OCAB	Office of the Assistant Secretary for Health, PHS
OCC	Operations Coordinating Committee
OCCC	Office of Clinical Center Communications
OCL	Office of Community Liaison (NIH OD)
OCPL	Office of Communications & Public Liaison
OD	Office of the Director, NIH
ODA	Official Duty Activities

ODEO	Office of the Director Executive Office (NIH OD)
ODEP	Office of Disability Employment Policy
ODP	Office of Disease Prevention (NIH OD)
ODS	Office of Dietary Supplements (NIH OD)
OE	Office of Education (NIH OD)
OEEO	Office of Equal Employment Opportunity (NIH OD)
OEO	Office of Equal Opportunity
OEODM	Office of Equality, Opportunity & Diversity Management
OEP	Office of Extramural Programs, OER, OD, NIH
OER	Office of Extramural Research, OD, NIH
OFACP	Office of Federal Advisory Committee Policy (NIH OD)
OFCCP	Office of Federal Contract Compliance Programs
OFM	Office of Financial Management
OFRM	Office of Financial Resources Management
OGC	Office of the General Counsel (NIH OD)
OGE	Office of Government Ethics
OHASIS	Office of Health and Safety Information System
OHER	Office of Health and Environmental Research
OHR	Office of Human Resources (NIH OD)
OHRM	Office of Human Resource Management (NIH OD)
OHRP	Office for Human Research Protections
OHS	Office of Healthy Start (HRSA)
OHSR	Office of Human Subjects Research
OIB	Office of Information Branch
OIG	Office of the Inspector General (USDA)

OIIA	Office of Intergovernmental and Interagency Affairs
OIR	Office of Intramural Research (NIH OD)
OIT	Office of Information Technology
OLAO	Office of Logistics and Acquisition Operations
OLAW	Office of Laboratory Animal Welfare, OER, OD, NIH
OLM	Office of Logistics Management
OLPA	Office of Legislative Policy and Analysis (NIH OD)
OLRS	Office of Loan Repayment and Scholarship (NIH OD)
OM	Office of Management (NIH OD)
OMA	Office of Management Assessment (NIH OD)
OMAR	Office of Medical Applications of Research (NIH OD)
OMB	Office of Management and Budget (White House)
OMBS	Office of Medical Board Services
OMH	Office of Minority Health (OASH)
OMS	Occupational Medical Services (DOHS)
ONC	Oncological Sciences
OPASI	Office of Portfolio Analysis and Strategic Initiatives (dissolved October 2008)
OPDIV	Operating Division (HHS)
OPEC	Office of Prevention, Education, and Control
OPERA	Office of Policy for Extramural Research Administration
OPF	Official Personnel File
OPHS	Office of Public Health and Science
OPL	Offices of Public Liaison (NIH OD)
OPM	Office of Personnel Management
OPRR	Office of Protection from Research Risks

ORA	Office of Reports and Analysis, OER, OD, NIH
ORD	Office of Rare Diseases (NIH OD)
ORI	Office of Research Integrity, HHS
ORIM	Office of Information Resources Management
ORS	Office of Research Services (NIH OD OM)
ORWH	Office of Research on Women's Health, OD, NIH
OS	Office of the Secretary
OSA	Office of Scientific Affairs, OER, OD, NIH
OSC	Office of Strategic Coordination, DPCPSI, OD, NIH
OSD	Office of the Scientific Director
OSE	Office of Science Education (NIH OD)
OSHA	Occupational Safety and Health Administration
OSHRC	Occupational Safety and Health Review Commission
OSMP	Office of Strategic Management and Planning (NIH OD)
OSP	Office of Science Policy (NIH OD)
OSPA	Office of Science Policy Analysis
OSPP	Office of Science Policy and Planning
OST	Office of Science and Technology
OSTI	Office of Scientific and Technical Information
OSTP	Office of Science and Technology Policy (White House)
OT	Overtime
OTA	Office of Technology Assessment
OTD	Office of Technology Development
OTS	Omega Travel Service (NIH Travel Agent)
OTT	Office of Technology Transfer

OUTPT	Outpatient
OWH	Office on Women's Health

P

P/TRP	Promotion/Tenure Review Panel
PA	Program Announcement
PA	Purchasing Agent
PAM	Office of Acquisition and Property Management
PAR	Program Announcement with special receipt or review
PART	Program Assessment Rating Tool (OMB)
PAS	Program Announcement with Set-aside funds
PCA	Physicians Comparability Allowance
PCBE	President's Council on Bioethics
PD	Position Description
PDF	Portable Document Format
PET	Positron Emission Tomography
PETA	People for the Ethical Treatment of Animals
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service (U.S.)
PHS OWH	U.S. Public Health Service's Office on Women's Health
PHTN	Public Health Training Network
PI	Principal Investigator
PIA	Procurement Integrity Act
PIN	Personal Identification Number
PKU	Phenylketonuria

PLC	Program Leadership Committee
PMCID	PubMed Central Identification
PMI	Presidential Management Intern
PMIS	Property Management Information System
PMO	Property Management Officer
PO	Program Official
PO	Project Officer (For a Grant or Contract)
PO	Purchase Order
Post-Doc	Post-Doctoral Fellow
PP	Pay Period
PPE	Pay Period Ending
PPP	Public Private Partnerships
PPS	Pathophysiological Sciences
PR	Public Relations
PRB	Protocol Review Board
PRC	Processing Resource Centers
Pre-Doc	Pre-Doctoral Fellow
PRG	Progress Review Groups
PRIMR	Public Responsibility in Medicine and Research
PRMC	Protocol Review and Monitoring Committee
Project EXPORT	Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training
PROTRACK	Clinical Center Protocol Tracking Database
PrP	Prion Protein
PRPL	Patient Recruitment and Public Liaison Office
PRRR	Program Review Report Record

PRS	Protocol Review Subcommittee
PSC	Program Support Center
PSC	Publications Subcommittee
PSO	Professional Service Order
PSP	Physician Special Pay (Title 38)
PTSD	Post-Traumatic Stress Disorder
PWS	Performance Work Statement

Q

Q&A	Questions and Answers
QA	Quality Assurance
QALY	Quality-Adjusted Life Years
QAP	Quality Assurance Program
QAS	Quality Assurance Subcommittee
QC	Quality Control
QRB	Quality Review Board
QSI	Quality Step Increase

R

R&D	Research & Development
R&W	Recreation and Welfare
R01	Standard NIH Research Project Grant
R34	Investigator-Initiated Clinical Trial Planning and Implementation Grants
R56	Grant allowing an interim award so principal investigator can continue while reapplying for an R01 grant. Also enables new investigators to gather preliminary data to improve their grant applications. (Bridge Award)

RA	Research Assistant
RAC	Recombinant-DNA Advisory Committee
RAID	Rapid Access to Intervention Development
RAL	Restored Annual Leave
RALAT	Registered Assistant Laboratory Animal Technician
RAO	Regulatory Affairs Officer
RCC	Research Coordination Council (Department-wide)
RCDA	Research Career Development Award (K-series awards)
RCDC	Research, Condition, and Disease Categorization
RCR	Responsible Conduct of Research
RCRII	RCMI Clinical Research Infrastructure Initiative
RCT	Randomized Controlled Trial
rDNA	Recombinant DNA
RePORT	NIH Research Portfolio Online Reporting Tools
RePORTER	RePort Expenditures and Results
RFA	Request for Application (request for grant applications for a research area)
RFC	Request For Contract
RFI	Request for Information
RFIP	Research Facilities Improvement Program
RFP	Request For Proposal (request for contract proposal for a project)
RFQ	Request for Quotation
RIF	Reduction In Force
RIMS	Robocom Inventory Management System
RISE	Research Initiative for Scientific Enhancement
RM	Roadmap

RMA	Risk Management Agency
RMS	Research Management Support
RNA	Ribonucleic Acid
RNAi	RNA interference
RPC	Review Policy Committee
RPG	Research Project Grant
RPHB	Risk, Prevention, and Health Behaviors
RPPR	Research Program Performance Report
RRTC	Regional Research and Training Center
RSA	Rehabilitation Services Administration
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSOB	Radiation Safety Operations Branch (DRS)
RSUM	Research Supplements for Underrepresented Minorities

S

SAC	Simplified Acquisition Committee
SAE	Serious Adverse Event
SAMHSA	Substance Abuse and Mental Health Services Administration, HHS
SB	Small Business
SBA	U.S. Small Business Administration
SBIR	Small Business Innovation Research
SBO	Small Business Office
SBRS	Senior Biomedical Research Service
SBS	Small Business Specialist

SBSA	Small Business Set-Aside
SC	Steering Committee
SCD	Service Computation Date
SCORE	Support of Continuous Research Excellence
SCR	Special Council Review
SD	Scientific Director
SDB	Small Disadvantaged Business
SEER	Surveillance, Epidemiology, and End Results
SE	Special Emphasis
SEP	Special Emphasis Panel (an SRG convened for a single meeting)
SES	Senior Executive Service
SF	Standard Form
SF	Staff Fellow
SIG	Shared Instrumentation Grant
SIMS	Scientific Initiative Management System
SIP	Summer Internship Program in Biomedical Research
SLA	Simple Letter of Agreement
SMSA	Small Business & Minority Business Set Aside
SNAP	Streamlined Noncompeting Award Process
SNEM	Social Science, Nursing, Epidemiology, and Methods
SNMA	Student National Medical Association
SNOMED	Systemized Nomenclature of Medicine
SNOMED CT	Systemized Nomenclature of Medicine – Clinical Terms
SNPs	Single Nucleotide Polymorphisms
SO	Signing Official

SOP	Standard Operating Procedure
SOW	Statement Of Work
SPA	Single Project Assurance
SPF	Specific-pathogen free
SPIN	Shared Pathology Informatics Network
SPORE	Specialized Program of Research Excellence
SRAs	Scientific Review Administrator (an NIH scientist administrator in charge of review and advisory groups; now called SROs)
SRB	Surgery, Radiology, and Bioengineering
SRB	Scientific Review Board
SREA	Scientific Review Evaluation Awards
SRFP	Summer Research Fellowship Program
SRG	Scientific Review Group (performs initial scientific merit review of grant application & contract proposals; also called Initial Review Group (IRG) when pertaining to grant applications)
SROs	Scientific Review Officer (manages the peer review process for grant applications and contract proposals; designated Federal official responsible for the peer review meeting; major focus is on scientific rather than administrative activities; former title was SRA)
SSB	Support Services Branch (DP)
SSEB	Source Selection Evaluation Board
SSF	Senior Staff Fellow
SSF	Service and Supply Fund
SSN	Social Security Number
SSS	Special Study Section
STD	Sexually Transmitted Disease
STDCRC	Sexually transmitted Disease Cooperative Research Centers
STDCTU	Sexually Transmitted Disease Clinical Trials Unit
STEP	Staff Training in Extramural Programs
STI	Scientific and Technical Information

STTR	Small Business Technology Transfer
SV	Student, or Special Volunteer

T

T&A	Time and Attendance
TAIMS	Time and Attendance Information Management System
TEHIP	Toxicology and Environmental Health Program
TIA	Time Off Incentive Award
TIG	Time In Grade
TIN	Payer Identification Number Tax
TK	Timekeeper
TMA	Tissue Microarray
TMJ	Temporomandibular joint
TO	Task Order
TOD	Tour of Duty
TOXNET	Toxicology Data Network
TQM	Total Quality Management
TSC	Training Subcommittee
TSP	Thrift Savings Plan
TTB	Technology Transfer Branch
TX	Treatment

U

U.S.C.	United States Code
UMLS	Unified Medical Language System

URC	User Resource Center
USAID	United States Agency for International Development
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USIA	United States Information Agency
USOPM	United States Office of Personnel Management
USUHS	Uniformed Services University of Health Sciences

V

VA	Veterans Administration
VA	Department of Veterans Affairs
VF	Visiting Fellow
VLTP	Voluntary Leave Transfer Program
VRC	Vaccine Research Center
VRP	Veterinary Resources Program
VS	Visiting Scientist
VSOF	Visual Status of Funds

W

WAG	Widely Attended Gathering
WFCL	Work and Family Life Center
WG	Wage Grade
WGI	Within-Grade Increase
WHI	Women's Health Initiative
WHO	World Health Organization, United Nations

WTO	World Trade Organization
WWW	World Wide Web
WYLBUR	Interactive system providing simultaneous service to more than 825 terminals or microcomputers.

X

X-Train	Trainee Activities System

Y

YTD	Year To Date

Z

ZIP (Code)	Zone Improvement Plan

National Institute of Diabetes and Digestive and Kidney Diseases Mission, Overview, and History

From 1950 until May 19, 1972, the Institute was known as the National Institute of Arthritis and Metabolic Diseases; until June 23, 1981, it was the National Institute of Arthritis, Metabolism, and Digestive Diseases; and until April 8, 1986, it was the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Mission

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.

OVERVIEW

The NIDDK supports a wide range of medical research through grants to universities and other medical research institutions across the country. The Institute also supports government scientists who conduct basic, translational, and clinical research across a broad spectrum of research topics and serious, chronic diseases and conditions related to the Institute's mission. In addition, the NIDDK supports research training for students and scientists at various stages of their careers and a range of education and outreach programs to bring science-based information to patients and their families, health care professionals, and the public.

External research funded by the NIDDK is organized into three scientific program divisions:

- Diabetes, Endocrinology, and Metabolic Diseases
- Digestive Diseases and Nutrition
- Kidney, Urologic, and Hematologic Diseases

The NIDDK's overarching principles in moving research forward include:

- maintaining a vigorous, investigator-initiated research portfolio that supports cross-cutting science that can be broadly applied to many disease-specific research areas
- supporting pivotal clinical studies and trials, with a focus on substantial participation of groups at highest risk.
- preserving a stable pool of talented new investigators
- fostering exceptional research training and mentoring opportunities
- ensuring that science-based health information reaches patients, their families, health care providers and the public through communications and outreach activities

Important Events in NIDDK History

August 15, 1950—President Harry S. Truman signed the Omnibus Medical Research Act into law, establishing the National Institute of Arthritis and Metabolic Diseases (NIAMD) in the U.S. Public Health Service. The new Institute incorporated the laboratories of the Experimental Biology and Medicine Institute, and expanded to include clinical investigation in rheumatic diseases, diabetes, and a number of metabolic, endocrine, and gastrointestinal diseases.

November 15, 1950—The National Advisory Arthritis and Metabolic Diseases Council held its first meeting and recommended approval of NIAMD's first grants.

1959—Dr. Arthur Kornberg, former chief of the Institute's enzyme and metabolism section, won the Nobel Prize for synthesizing nucleic acid.

1961—Laboratory-equipped mobile trailer units began an epidemiological study of arthritis among the Blackfeet and Pima Indians in Montana and Arizona, respectively.

October 16, 1968—The Nobel Prize was awarded to Dr. Marshall W. Nirenberg of the National Heart Institute, who reported his celebrated partial cracking of the genetic code while an NIAMD scientist.

November 1970—The Institute celebrated its 20th anniversary. U.S. Secretary of Defense Melvin R. Laird addressed leaders in the department, representatives from voluntary health agencies and professional biomedical associations, and past and present Institute National Advisory Council members.

May 19, 1972—The Institute's name was changed to the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD).

October 1972— Dr. Christian B. Anfinsen, chief of the Institute's Laboratory of Chemical Biology, shared a Nobel Prize with two other American scientists for demonstrating one of the most important simplifying concepts of molecular biology: that the three-dimensional conformation of a native protein is determined by the chemistry of its amino acid sequence. A significant part of the research cited by the award was performed while Anfinsen was with the NIH.

September 1973—The creation of the first Diabetes-Endocrinology Research Centers marked the beginning of the Institute’s Diabetes Centers Program.

November 1975—After nine months of investigation into the epidemiology and nature of diabetes mellitus and public hearings throughout the United States, the National Commission on Diabetes delivered its report, the *Long-Range Plan to Combat Diabetes*, to Congress. Recommendations included expanding and coordinating diabetes and related research programs; creating a diabetes research and training centers program; accelerating diabetes health care, education, and control programs; and establishing a National Diabetes Advisory Board.

April 1976—The National Commission on Arthritis and Related Musculoskeletal Diseases issued *The Arthritis Plan*. This report to Congress called for increased arthritis research and training programs, multipurpose arthritis centers, epidemiologic studies and data systems in arthritis, a National Arthritis Information Service, and a National Arthritis Advisory Board.

October 1976—Dr. Baruch Blumberg was awarded the Nobel Prize in Physiology or Medicine for research on the hepatitis B virus protein, the "Australia antigen," which he discovered in 1963 while at the Institute. This advance has proven to be a scientific and clinical landmark in detecting and controlling viral hepatitis and led to the development of preventive measures against hepatitis and liver cancer.

April 19, 1977—The NIH director established a trans-NIH program for diabetes, with the NIAMDD taking lead responsibility.

September 1977—Over $5 million in grants was awarded to 5 institutions to establish Diabetes Research and Training Centers.

October 1977—In response to the recommendation of the National Commission on Diabetes, the National Diabetes Data Group was established within the Institute to collect, analyze, and disseminate diabetes data to scientific and public health policy and planning associations.

December 1977—Institute grantees Drs. Roger C.L. Guillemin and Andrew V. Shally shared the Nobel Prize in Physiology or Medicine with a third scientist. Guillemin's and Shally's prizes were for discoveries related to the brain's production of peptide hormones.

1978—The NIDDK created the National Diabetes Information Clearinghouse to increase knowledge and understanding about diabetes among people with these conditions and their families, health professionals, and the general public.

January 1979—The National Commission on Digestive Diseases issued the report, The *National Long-Range Plan to Combat Digestive Diseases*. Recommendations to Congress included establishing a National Digestive Diseases advisory board and information clearinghouse, and emphasizing digestive diseases educational programs more in medical schools.

June 1980—The NIDDK created the National Digestive Diseases Information Clearinghouse to increase knowledge and understanding about digestive diseases among people with these conditions and their families, health professionals, and the general public.

September 1980—Dr. Joseph E. Rall, director of NIAMDD intramural research, became the first person at the NIH to be named to the distinguished executive rank in the Senior Executive Service. President Jimmy Carter presented the award in ceremonies at the White House on September 9.

October 15, 1980—NIAMDD celebrated its 30th anniversary with a symposium, "DNA, the Cell Nucleus, and Genetic Disease." Dr. Donald W. Seldin, chairman of the department of internal medicine, University of Texas Southwestern Medical School, Dallas, was guest speaker.

1981—A report entitled *An Evaluation of Research Needs in Endocrinology and Metabolic Diseases* was prepared by an external group of scientific experts, and was submitted to the NIH and the Senate Committee on Appropriations.

June 23, 1981—The Institute was renamed the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

April 1982—U.S. Department of Health and Human Services (HHS) Secretary Richard S. Schweiker elevated the NIADDK's programs to division status, creating five extramural divisions and the Division of Intramural Research.

November 1982—Dr. Elizabeth Neufeld, chief of the NIADDK's genetics and biochemistry branch, received a Lasker Foundation Award. She was cited, along with Dr. Roscoe E. Brady of the then-named National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), for "significant and unique contributions to the fundamental understanding and diagnosis of a group of inherited diseases called mucopolysaccharide storage disorders (MPS)."

November 1984—Grants totaling more than $4 million were awarded to six institutions to establish the Silvio O. Conte Digestive Diseases Research Centers. The research centers investigate the underlying causes, diagnoses, treatments, and prevention of digestive diseases.

April 8, 1986—The Institute's Division of Arthritis, Musculoskeletal and Skin Diseases became the core of the new National Institute of Arthritis and Musculoskeletal and Skin Diseases. The NIADDK was renamed the National Institute of Diabetes and Digestive and Kidney Diseases.

June 3, 1986—The National Kidney and Urologic Diseases Advisory Board was established to formulate the long-range plan to combat kidney and urologic diseases.

1987—The NIDDK created the National Kidney and Urologic Diseases Information Clearinghouse to increase knowledge and understanding about diseases of the kidneys and urologic system among people with these conditions and their families, health care professionals, and the general public.

August 1, 1987—Six institutions were funded to establish the George M. O'Brien Kidney and Urological Research Centers.

December, 1987—In response to congressional language on the fiscal year (FY) 1988 appropriation for the NIDDK, the Institute established a program of cystic fibrosis research centers.

March, 1990—The National Kidney and Urologic Diseases Advisory Board issued its "Long-Range Plan: Window on the 21st Century." The Plan presented recommendations for uniting the

public and private sectors in the quest to prevent these diseases; improve methods for early detection, treatment, and rehabilitation; and ultimately find cures.

September 16, 1990—The NIDDK celebrated its 40th anniversary. Dr. Daniel E. Koshland, Jr., editor of *Science*, was guest speaker.

June, 1991—The NIDDK Advisory Council established the National Task Force on the Prevention and Treatment of Obesity to synthesize current science on preventing and treating obesity and to develop statements about topics of clinical importance based on critical analyses of the scientific literature.

September 30, 1992—Three Obesity/Nutrition Research Centers were established, along with an extramural animal models core to breed genetically obese rats for obesity and diabetes research.

October 12, 1992—Drs. Edwin G. Krebs and Edmond H. Fischer were awarded the Nobel Prize in Physiology or Medicine for their work on "reversible protein phosphorylation." At the time of the award, the scientists had been receiving continuous NIDDK grant support since 1951 and 1956, respectively.

October 30, 1992—In response to congressional language on the Institute's FY 1993 appropriation, the NIDDK initiated a program to establish gene therapy research centers with emphasis on cystic fibrosis.

November 1, 1993—The functions of the NIH Division of Nutrition Research Coordination, including those of the NIH Nutrition Coordinating Committee, were transferred to the NIDDK.

October 10, 1994—Drs. Martin Rodbell and Alfred G. Gilman received the Nobel Prize in Physiology or Medicine for discovering G-proteins, a key component in the signaling system that regulates cellular activity. Dr. Rodbell discovered the signal transmission function of GTP while a researcher at the then-named NIAMD.

June 22, 1997—Led by the NIDDK, the NIH and the U.S. Centers for Disease Control and Prevention (CDC) announced the creation of the National Diabetes Education Program (NDEP) at the American Diabetes Association annual meeting in Boston. The NDEP's goals are to reduce the rising prevalence of diabetes, the morbidity and mortality of the disease, and its complications.

July 18, 2000—The NIDDK created the National Kidney Disease Education Program to raise awareness among the public of kidney disease and its risk factors, and make resources available to consumers and health care providers.

June 2000—To reduce the disproportionate burden of many diseases in minority populations, the NIDDK initiated an Office of Minority Health Research Coordination.

November 16, 2000—The NIDDK celebrated its 50th anniversary. Professional societies in eight U.S. locations and Canada sponsored scientific symposia and hosted an NIDDK exhibit. In addition, *A New Century of Science*: *A New Era of Hope* was published to highlight research supported and conducted by the NIDDK. The Institute concluded the year with a joint scientific symposium at the Society for Cell Biology's 40th anniversary meeting in December.

October 8, 2003—NIDDK grantee Dr. Peter Agre shared the Nobel Prize in Chemistry with another scientist for studies of channels in cell membranes. Agre discovered aquaporins, proteins that move water molecules through the cell membrane.

October 4, 2004—Dr. Richard Axel, once an intramural research fellow under Dr. Gary Felsenfeld at the NIDDK, shared the Nobel Prize in Physiology or Medicine with another scientist for discovering a large family of receptors selectively expressed in cells that detect specific odors.

October 6, 2004—Long-time grantees Drs. Irwin A. Rose and Avram Hershko shared the Nobel Prize in Chemistry with another scientist for discovering ubiquitin-mediated protein degradation inside the cell.

October 2007—Institute grantee Dr. Oliver Smithies shared the Nobel Prize in Physiology or Medicine with two other scientists for discovering principles for introducing specific gene modifications in mice by using embryonic stem cells.

2010—The NIDDK celebrated its 60th anniversary. Special events included the September 21 scientific symposium "Unlocking the Secrets of Science: Building the Foundation for Future Advances" and the publication of the commemorative report *NIDDK: 60 Years of Advancing Research to Improve Health.*

September 2010—NIDDK grantee Dr. Jeffrey Friedman and former grantee Dr. Douglas Coleman won the 2010 Albert Lasker Basic Medical Research Award for discovering the hormone leptin, which plays a key role in regulating energy intake and energy expenditure.

October 3, 2011—NIDDK grantee Dr. Bruce Beutler shared the 2011 Nobel Prize in Physiology or Medicine with NIH grantee Dr. Jules Hoffman for their discoveries concerning the activation of innate immunity. NIH grantee Dr. Ralph Steinman also shared the award posthumously for his discovery of the dendritic cell and its role in adaptive immunity.

December 2011—The journal *Science* named an HIV-prevention research study led by NIDDK grantee Dr. Myron Cohen the 2011 Breakthrough of the Year. The study found that people infected with HIV reduced the risk of transmitting the virus to their sexual partners by taking oral antiretroviral medicines when their immune systems were relatively healthy. Cohen, an NIH MERIT Award recipient, has received more than 20 years of continuous NIH funding, including NIDDK funding for basic science research earlier in his career.

April 29, 2012—The Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) study, the results of which appeared in the New England Journal of Medicine on April

29, 2012, is the first major comparative effectiveness trial for the treatment of type 2 diabetes in young people. The NIDDK-funded study found that combined therapy with metformin and rosiglitazone was superior to metformin alone. The rate of treatment failure with metformin alone suggested that most youth with type 2 diabetes will require combination treatment or insulin within a few years after diagnosis.

September 21, 2012—Dr. Thomas E. Starzl, distinguished service professor of surgery at the University of Pittsburgh School of Medicine and a longtime NIDDK grantee, received the 2012 Lasker-DeBakey Clinical Medical Research Award – shared with Dr. Roy Calne, University of Cambridge emeritus — for his work developing liver transplantation, an intervention that has restored normal life to thousands of people with end-stage liver disease.

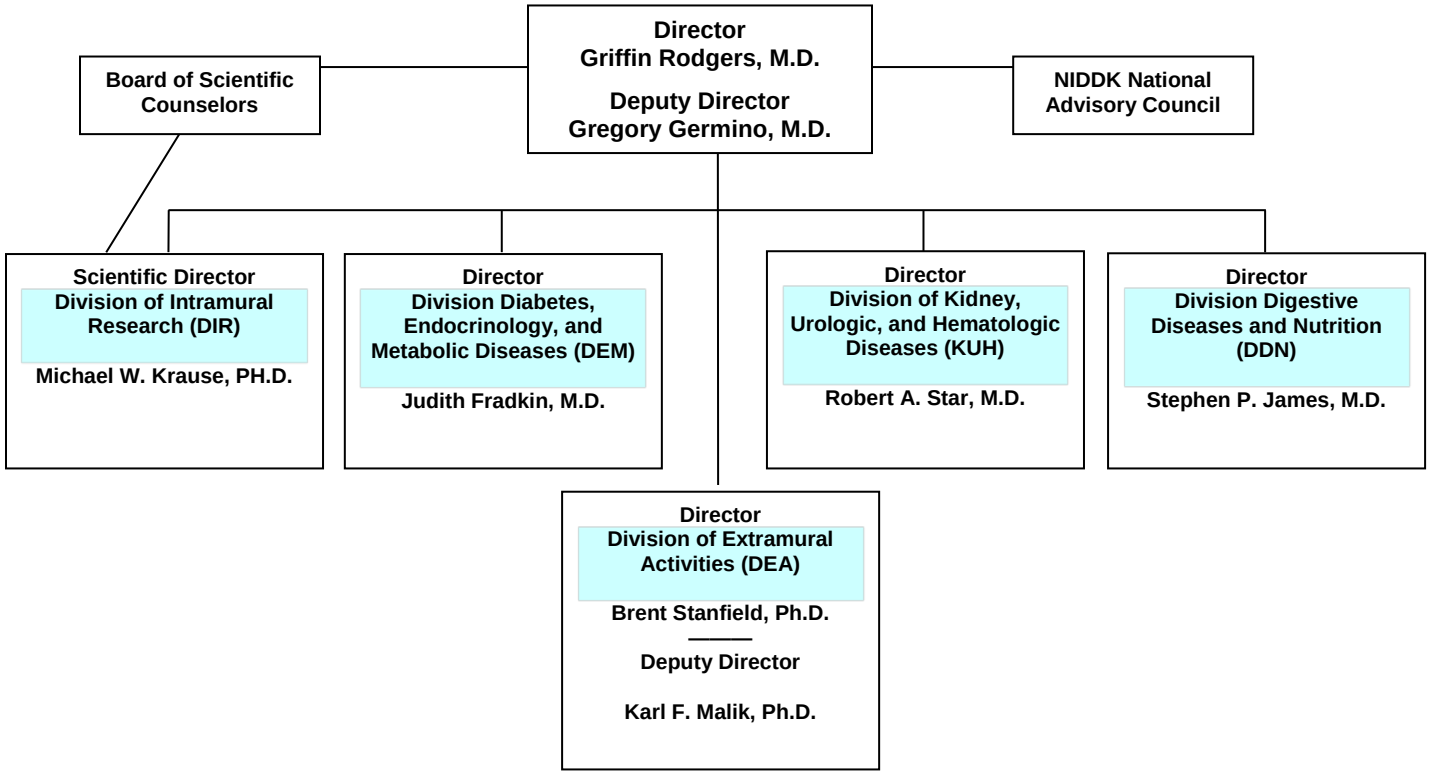
October 2012—Dr. Robert J. Lefkowitz, who trained at NIDDK from 1968-1970 as a clinical associate in the Clinical Endocrinology Branch, won the 2012 Nobel in chemistry for studies of protein receptors that let body cells sense and respond to outside signals.

October 2013—Dr. James Rothman, an NIDDK grantee, received the 2013 Nobel Prize in physiology or medicine, shared with fellow NIH grantees Drs. Randy W. Schekman and Thomas C. Südhof “for their discoveries of machinery regulating vesicle traffic, a major transport system in our cells,” according to the Nobel organization. The researchers’ work revealed how cells use small sacs, called vesicles, to import and export materials to and from cells. This transport system is a fundamental process in how cells work.

NIDDK Directors

Name	In Office from	To
William Henry Sebrell, Jr.	August 15, 1950	October 1, 1950
Russell M. Wilder	March 6, 1951	June 30, 1953
Floyd S. Daft	October 1, 1953	May 3, 1962
G. Donald Whedon	November 23, 1962	September 30, 1981
Lester B. Salans	June 17, 1982	June 30, 1984
Mortimer B. Lipsett	January 7, 1985	September 4, 1986
Phillip Gorden	September 5, 1986	November 14, 1999
Allen M. Spiegel	November 15, 1999	March 3, 2006
Griffin P. Rodgers	April 1, 2007	present

NIDDK Organizational Chart



Overview of the Office of the Director

In addition to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC), the Office of the Director includes the following offices:

- Executive Office, including administrative components:
  - — Ethics Office
  - — Office of Workforce Development and Planning (OWDP)
  - — Office of Management and Policy Analysis (OMPA)
  - — Office of Financial Management and Analysis (OFMA)
  - — Extramural Administrative Management Branch (EAMB)
  - — Intramural Administrative Management Branch (IAMB)
  - — Computer Technology Branch (CTB)
  - — Technology Transfer and Development Branch
- Office of Communications and Public Liaison (OCPL)
- Office of Scientific Program and Policy Analysis (OSPPA)

Also within the Office of the Director are the following two research coordination offices.

The NIDDK director created the ***Office of Minority Health Research Coordination*** *(OMHRC)* to address the burden of diseases and disorders that disproportionately impact the health of minority populations. The OMHRC will help implement the Institute's strategic plan for health disparities and build on the strong partnership with the National Center on Minority Health and Health Disparities at NIH.

The NIDDK ***Office of Obesity Research*** (OBR) is responsible for coordination of obesity-related research within NIDDK, and carries out its functions through the NIDDK Obesity Research Working Group. The Office is located organizationally under the auspices of the Office of the Director, NIDDK, and its co-directors represent the two divisions with primary responsibility for obesity-related extramural research, the Division of Digestive Diseases and Nutrition (DDN) and the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM). The Obesity Research Working Group consists of representatives of DDN, DEM, the Division of Kidney, Urologic, and Hematologic Diseases (KUH), the NIDDK Review Branch, the Office of Scientific Program and Policy Analysis (OSPPA), and the Division of Nutrition Research Coordination (DNRC). The responsibilities of the NIDDK Obesity Research Working Group are: (1) to provide a forum for sharing and coordination of trans-NIDDK and trans-NIH obesity research activities; (2) to assist the Director, NIDDK in identifying research opportunities, initiatives, and advances; (3) to identify and plan appropriate workshops and conferences; and (4) to assist in the preparation of obesity-related reports and inquiries.

The ***Office of Nutrition Research*** (ONR) is responsible for leadership of nutrition research in NIDDK and collaboratively, across NIH institutes. The office participates in strategic planning, portfolio analysis, budget and resource allocation, and assessment of research needs and opportunities that fall within the mission of NIDDK and the NIH. Strategic planning includes developing new NIH research initiatives in nutrition research. The office replaces the NIH Division of Nutrition Research Coordination (DNRC).

Under the auspices of the NIDDK Advisory Council, the National Task Force on Prevention and Treatment of Obesity was established in June 1991. In June 2003, the name was changed to the *Clinical Obesity Research Panel (CORP)*. The mission of the CORP is to synthesize current scientifically based information on the prevention and treatment of obesity and to develop statements about topics of clinical importance that are based on critical analyses of the literature. It is composed of leading obesity researchers and clinicians who advise the institute on research needs and sponsor workshops on topics

related to the prevention and treatment of obesity. The CORP serves in an advisory capacity to the Weight-control Information Network (WIN).

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Overview of the Division of Intramural Research

The Division of Intramural Research oversees research and training conducted within the NIDDK's laboratories and clinical facilities by government scientists in Bethesda, MD, and Phoenix, AZ. Several of NIDDK's intramural scientists have received national and international awards for scientific excellence.

The division includes 10 branches, nine laboratories, and four offices, which focus on issues of technology transfer, fellow recruitment and career development, and the overall management of the division's basic and clinical research efforts. In addition, nine core facilities provide centralized scientific support services to the laboratories and branches.

The intramural branches conduct basic, translational, and clinical biomedical research related to diabetes mellitus, endocrine, bone and metabolic diseases; digestive diseases, including liver diseases and nutritional disorders; kidney diseases; and hematologic diseases. The NIDDK's intramural labs are involved in fundamental research in biophysics; cell biology; chemical biology and medicinal chemistry; developmental biology; genetics, pathogenesis, and novel therapies of disease; molecular biology; signal transduction; and structural biology

Website: http://www.niddk.nih.gov/research-funding/at-niddk/Pages/default.aspx

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The DEA is organized into three primary components:

- the Grants Management Branch, the focal point for all business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements within the NIDDK
- the Scientific Review Branch, which coordinates the initial scientific peer review of applications submitted in response to Request for Applications (RFAs), training and career awards, program projects, multi-center clinical trials, and research contracts, including Loan Repayment Program applications. Most R01s, fellowship, and SBIR grant applications are reviewed in the Center for Scientific Review.
- the Office of Research Evaluation and Operations (OREO), within the DEA Office of the Director, oversees and coordinates disease coding/reporting for the NIDDK extramural program, manages the Early Notification System and NIH Guide publication process associated with publishing Funding Opportunity Announcements, and supports NIDDK Advisory Council activities. The office also facilitates harmonization of activities among NIDDK's four extramural divisions, and coordinates/performs special projects at the request of the NIDDK leadership.

Website: http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/Pages/default.aspx

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Overview of the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM)

The Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM) supports research, research training, and career development related to a vast and diverse range of diseases and conditions, including diabetes mellitus, obesity, osteoporosis, cystic fibrosis, thyroid and other endocrine disorders, and metabolic diseases. The division also leads the administration of trans-NIH diabetes research; coordinates federally supported, diabetes-related activities; promotes public awareness and education about diabetes and other diseases; and collects and disseminates data.

Diabetes Research Programs

The division encompasses 18 diabetes research programs, including the

- Clinical Research in Type 1 Diabetes
- Clinical Research in Type 2 Diabetes
- Clinical, Behavioral, and Epidemiological Obesity Research
- Diabetes and Endocrine Disease Bioengineering, Biotechnology, and Imaging
- Diabetes and Metabolism HIV/AIDS
- Diabetes Centers
- Diabetes Genetics and Genomics
- Diabetes, Endocrine, and Metabolic Disease Translational Research
- Diabetes: Treatment, Prevention, and Complications
- Diabetic Kidney Disease
- Diabetic Urologic Disease
- Endocrine Pancreas
- Endocrinology and Hormone Signaling
- Genetic Metabolic Disease
- Kidney Genetics and Genomics
- Metabolic Pathways
- Obesity, Pregnancy, and the Intrauterine Environment
- Pathophysiology of Diabetes and Metabolic Disease

Endocrine and Metabolic Diseases Research Programs

The division encompasses seven endocrinology research programs, including the

- Chronic Kidney Disease
- Clinical, Behavioral, and Epidemiological Obesity Research
- Cystic Fibrosis Research and Translation Centers
- Cystic Fibrosis, CTFR
- Diabetes and Endocrine Disease Bioengineering, Biotechnology, and Imaging
- Diabetes and Metabolism HIV/AIDS
- Diabetes, Endocrine, and Metabolic Disease Translational Research
- Endocrine Pancreas
- Endocrine Tumors of the Pancreas
- Endocrinology and Hormone Signaling
- Genetic Metabolic Disease
- Metabolic Pathways

- Metabolism, Energy Balance, and Obesity
- Nutrient Metabolism, Status, and Assessment
- Obesity, Pregnancy, and the Intrauterine Environment
- Pathophysiology of Diabetes and Metabolic Disease

Diabetes Mellitus Interagency Coordinating Committee

The Diabetes Mellitus Interagency Coordinating Committee (DMICC) coordinates diabetes research and activities across the NIH and other federal programs. The division director chairs the DMICC, which includes representatives from all federal departments and agencies whose programs involve health functions and responsibilities relevant to diabetes and its complications.

National Diabetes Data Group

The DEM's National Diabetes Data Group serves as the federal lead for collecting, analyzing, and sharing data on diabetes and its complications. The group draws on the expertise of the research, medical, and lay communities to support its data initiatives.

National Diabetes Education Program
See "Health Information and Education Services."

Website: http://www.niddk.nih.gov/about-niddk/staff-directory/staff-by-office/division-diabetes-endocrine-metabolic-diseases/Pages/Division-of-Diabetes,-Endocrine-and-Metabolic-Diseases.aspx

How To Contact Us

Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM)

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Abraham, Kristin	Program Director	The role of inflammation in the pathophysiology of metabolic disease and the use of mouse models in metabolic phenotyping	abrahamk@mail.nih.gov 301-451-8048
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Brathwaite, Debbie	Support Assistant (Contractor)	Administrative support for the scientific staff	debbie.brathwaite@nih.gov 301-594-4703
Bremer, Andrew	Program Director	Basic science and clinical research focused on the prevention and treatment of type 2 diabetes; diet and exercise in the prevention and management of type 2 diabetes; gestational diabetes and maternal outcomes; and HIV and HIV-treatment associated metabolic/endocrine dysfunction	andrew.bremer@nih.gov 301-402-7886
Castle, Arthur	Program Director	Functional metabolomics and technology development to measure integrated metabolism in the etiology of metabolic disease; fellowships and institutional training grants	castlea@mail.nih.gov 301-594-7719
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Hyde, James	Program Director	Neurobiology of energy balance and body composition in obesity; Diabetes Research Centers; career development (“K”) programs	hydej@mail.nih.gov 301-594-7692
Jones, Teresa	Program Director	Basic and clinical research related to the complications of Type 1 and Type 2 diabetes	jonester@mail.nih.gov 301-435-2996
Laughlin, Maren	Program Director	Integrative metabolism and physiology, and in vivo molecular and functional imaging, as relevant to energy balance in metabolic disease	laughlinm@mail.nih.gov 301-594-8802
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Pawlyk, Aaron	Program Director	Key regulators of intermediary metabolism; drug discovery; pharmacogenetics and precision medicine.	pawlykac@mail.nih.gov 301-451-7299
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Savage, Peter	Program Director	Clinical research in Type 1 and Type 2 Diabetes including secondary analyses; glycemic control and preservation of beta cell function	savagep@niddk.nih.gov 301-594-8858

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Silva, Corinne	Program Director	Signaling pathways, including nuclear receptors, and nutrient sensing in metabolic tissues; role of intrauterine environment in offspring metabolic disease	silvacm@mail.nih.gov 301-451-7335
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Staten, Myrlene	Program Director (Contractor)	Pharmacologic interventions and/or other medically related interventions to prevent or treat Type 2 Diabetes in adult patients	statenm@niddk.nih.gov 301-402-3151
Stoeckel, Luke	Program Director	Cognitive and clinical neuroscience of the non-homeostatic (i.e., extra-hypothalamic) contributions to obesity and diabetes and their complications.	luke.stoeckel@nih.gov 301-594-8810
Teff, Karen	Program Director	Effects of bariatric surgery on diabetes and related metabolic outcomes; prevention, treatment and pathophysiology of hypoglycemia; effects of sleep/circadian as well as autonomic nervous system effects on diabetes-related metabolism in humans; clinical and basic research on intermediary hepatic metabolism	karen.teff@nih.gov 301-594-8803

Overview of the Division of Digestive Diseases and Nutrition

The Division of Digestive Diseases and Nutrition (DDN) supports research related to digestive diseases, including the alimentary tract, liver and pancreas, nutrition and obesity. The programs include basic, translational and clinical research. DDN also promotes public awareness and education about digestive diseases and related conditions, and oversees several national public awareness campaigns.

Digestive Diseases Research Programs

Alimentary tract programs

- Digestive Diseases Clinical Research and Epidemiology
- Digestive Diseases Genetics and Genomics
- Digestive Diseases Research Core Centers
- Gastrointestinal Immunology, Inflammation, and Inflammatory Diseases
- Gastrointestinal Microbiology and Infectious Diseases
- Gastrointestinal Neuroendocrinology
- Gastrointestinal Physiology, Development, and Epithelial Biology
- Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS
- Motility and Functional Gastrointestinal Disorders
- Nutrient Metabolism, Status, and Assessment

Liver Disease Research Programs

- Clinical, Behavioral, and Epidemiological Obesity Research
- Digestive Diseases Research Core Centers
- Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS
- Genetic Metabolic Disease
- Iron and Heme Metabolism, Iron Chelation
- Liver Clinical Research and Epidemiology
- Liver Diseases Genetics and Genomics
- Nutrient Metabolism, Status, and Assessment
- Translational and Basic Liver Disease Research

Pancreas Research Programs

- Acute and Chronic Pancreatitis
- Endocrine Pancreas
- Endocrine Tumors of the Pancreas
- Hereditary and Pediatric Disorders of the Pancreas
- Pancreas Basic Research and Development
- Pancreas Clinical Research and Epidemiology

Obesity Research Programs

- Chronic Kidney Disease
- Clinical, Behavioral, and Epidemiological Obesity Research
- Endocrinology and Hormone Signaling
- Metabolic Pathways
- Metabolism, Energy Balance, and Obesity
- Neurobiology of Obesity
- Nutrient Metabolism, Status, and Assessment
- Nutrition and Obesity Genetics and Genomics
- Nutrition Obesity Research Centers
- Obesity Treatment and Prevention
- Obesity, Pregnancy, and the Intrauterine Environment

Cross-cutting programs

- Career Development
- Digestive Diseases Centers
- Loan Repayment
- Nutrition Obesity Research Centers
- Small Business
- T32 Training

The division oversees the following health education and awareness campaigns:

- Celiac Disease Awareness Campaign
- Ways to Enhance Children's Activity and Nutrition (We Can!)
- Weight-control Information Network
- Bowel Control Awareness Campaign

For more information about these initiatives, see "Health Information and Education Services."

Website: http://www.niddk.nih.gov/health-information/Pages/default.aspx

How To Contact Us

Division of Digestive Diseases and Nutrition (DDN)

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Liver Diseases Research Branch

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Overview of the Division of Kidney, Urologic, and Hematologic Diseases

The Division of Kidney, Urologic, and Hematologic (KUH) Diseases provides research funding and support for basic, translational, and clinical research studies of the kidney, urinary tract, and disorders of the blood and blood-forming organs. The division also provides funding for training and career development of people committed to academic and clinical research in these areas.

Kidney Diseases Research Programs

The division encompasses research programs related to kidney research, including

- Acute Kidney Injury
- Chronic Kidney Disease
- Diabetic Kidney Disease
- End-Stage Renal Disease
- Genetic Metabolic Disease
- Kidney Basic Research
- Kidney Bioengineering, Biotechnology, and Imaging
- Kidney Clinical Research and Epidemiology
- Kidney Developmental Biology and Aging
- Kidney Disease Centers
- Kidney Genetics and Genomics
- Kidney HIV/AIDS
- Kidney Inflammation and Inflammatory Diseases
- Pediatric Kidney Disease
- Polycystic Kidney Disease

Urological Diseases Research Programs

The division encompasses research programs related to urology research, including

- Diabetic Urologic Disease
- Genetic Metabolic Disease
- Pediatric Urology
- Urologic Disease Centers
- Urology Basic Research
- Urology Bioengineering, Biotechnology, and Imaging
- Urology Clinical Research and Epidemiology
- Urology Developmental Biology and Aging
- Urology Genetics and Genomics
- Urology HIV/AIDS
- Women’s Urology

Hematology Research Programs

The division encompasses research programs related to hematology research, including the

- Erythropoiesis and Hemoglobin
- Genetic Metabolic Disease
- Hematology HIV/AIDS
- Hematopoiesis and Hematopoietic Stem Cell Biology
- Iron and Heme Metabolism, Iron Chelation
- Molecular Hematology Centers

The division oversees the following health education and awareness campaigns:

- Bladder Control for Women
- National Kidney Disease Education Program

For more information about these initiatives, see "Health Information and Education Services."

Website: http://www.niddk.nih.gov/health-information/Pages/default.aspx

How To Contact Us

Division of Kidney, Urologic, and Hematologic Diseases

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Funding Mechanisms (Activity Codes) Supported by NIDDK

Brief Overview

An Activity Code is a three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). General categories include:

- F – fellowships
- K – career development awards
- N – research contracts
- P – program project and research center grants
- R – research project grants
- S – research-related programs
- T – training grants
- U – cooperative agreements
- Y – interagency agreements

Extramural research activities are divided into three main mechanisms: grants, cooperative agreements, and contracts. A mechanism is the type of funding instrument used at the NIH. In general, with grants (all activity codes other than "N" or "U"), investigators are responsible for developing the concepts, methods, and approach for a research project. With contracts ("N" series), the DHHS awarding unit is responsible for establishing the detailed requirements. With cooperative agreements ("U" series), both the awarding unit and the recipient have substantial responsibility. Programs are areas within the funding mechanisms (for example, research, training, fellowships, and cooperative agreements). Activity codes identify categories applied to various mechanisms.

For NIH-wide activity codes and definitions beyond the NIDDK codes listed below, go to Types of Grant Programs page (http://grants.nih.gov/grants/funding/funding_program.htm) to search activity codes or to the comprehensive list of extramural grant and cooperative agreement activity codes for more information on selected grant programs.

Special NIH-Wide Programs

DP1 **NIH Director's Pioneer Award** (NDPA) (Roadmap program)
To support individuals who have the potential to make extraordinary contributions to medical research. The NDPA is not renewable.

DP2 **NIH Director's New Innovator Awards** (Roadmap program)
To support highly innovative research projects by new investigators in all areas of biomedical and behavioral research.

DP3 **Type 1 Diabetes Targeted Research Award**
To support research tackling major challenges in type 1 diabetes and promoting new approaches to these challenges by scientific teams.

Fellowship Programs

F 31 **Predoctoral Individual National Research Service Award**
To provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

F 32 **Postdoctoral Individual National Research Service Award**
To provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

F 33 **National Research Service Awards for Senior Fellows**
To provide opportunities for experienced scientists to make major changes in the direction of research careers, to broaden scientific background, to acquire new research capabilities, to enlarge command of an allied research field, or to take time from regular professional responsibilities for the purpose of increasing capabilities to engage in health-related research.

Research Career Programs

K 01 **Research Scientist Development Award - Research & Training**
For support of a scientist, committed to research, in need of both advanced research training and additional experience.

K 08 **Clinical Investigator Award (CIA)**
To provide the opportunity for promising medical scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research aspects of categorical areas applicable to the awarding unit, and aid in filling the academic faculty gap in these shortage areas within health profession's institutions of the country.

K 12 **Physician Scientist Award (Program) (PSA)**
For support to a newly trained clinician appointed by an institution for development of independent research skills and experience in a fundamental science within the framework of an interdisciplinary research and development program.

K 18 **The Career Enhancement Award**
To provide either full-time or part-time support for experienced scientists who wish to broaden their scientific capabilities or to make changes in their research careers by acquiring new research skills or knowledge. Career enhancement experiences supported by this award should usually last no more than one year.

K 22 **Career Transition Award**
To provide support to outstanding newly trained basic or clinical investigators to develop their independent research skills through a two phase program; an initial period involving and intramural appointment at the NIH and a final period of support at an extramural institution. The award is intended to facilitate the establishment of a record of independent research by the investigator in order to sustain or promote a successful research career.

K 23 **Mentored Patient-Oriented Research Career Development Award**
To provide support for the career development of investigators who have made a commitment of focus their research endeavors on patient-oriented research. This mechanism provides support for a 3 year minimum up to 5 year period of supervised study and research for clinically trained professionals who have the potential to develop into productive, clinical investigators.

K 24 **Midcareer Investigator Award in Patient-Oriented Research**
To provide support for the clinicians to allow them protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators.

K 25 **Mentored Quantitative Research Career Development Award**
To engender and foster such activities by supporting the career development of investigators with quantitative scientific and engineering backgrounds outside of biology or medicine who have made a commitment to focus their research endeavors on behavioral and biomedical research (basic or clinical). This mechanism is aimed at research-oriented scientists with experience at the level of junior faculty (e.g., early to mid-levels of assistant professor or research assistant professor ranks). This award provides support for a period of mentored study and research for professionals with such backgrounds who have the potential to integrate their expertise with biomedicine and develop into productive investigators.

Examples of quantitative scientific and technical backgrounds outside of biology or medicine considered appropriate for this award include, but are not limited to: mathematics, statistics, computer science, informatics, physics, chemistry, and engineering.

K 30 **Clinical Research Curriculum Award (CRCA)**
The CRCA is an award to institutions and is intended to stimulate the inclusion of high-quality, multi-disciplinary didactic training as part of the career development of clinical investigators. This award is intended to support the development of new didactic programs in clinical research at institutions that do not currently offer such programs or, in institutions with existing didactic programs in clinical research to support or expand their programs or to improve the quality of instruction.

K 99 **NIH Pathway to Independence Award (PI)**
R 00 To provide an opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award. The primary purpose of the Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented NIH-supported independent investigators. The initial phase (K99 Career Transition Award) provides 1-2 years of mentored support for highly motivated, advanced postdoctoral research scientists. The second phase (R00 Research Transition Award) provides 1-3 years of independent research support contingent on securing an independent research position. Award recipients will be expected to compete successfully for independent R01 support from the NIH during the R00 research transition award period.

KM1 **Institutional Career Enhancement Awards - Multi-Yr Funding**
Provides for part-time (minimum 25% effort) up to full-time support for medical, scientific, statistics and health care professionals with post-doctoral or equivalent experience selected by an institution, to broaden their research capabilities by acquiring new research skills or knowledge. Further it provides for curriculum development of new programs to support these same types of individuals. This is an institutional mentored career program, not an individual program. It is also a multi-year funded institutional mentored career development activity thus ICs need OER prior approval to use the KM1.

Extramural Loan Repayment Program

L 30 **Loan Repayment Program for Clinical Researchers**
To provide for the repayment of the educational loan debt of qualified health professionals involved in clinical research. Qualified health professionals who contractually agree to conduct qualified clinical research are eligible to apply for this program.

L 40 **Loan Repayment Program for Pediatric Research**
To provide for the repayment of the educational loan debt of qualified health professionals involved in research directly related to diseases, disorders, and other conditions in children.

Qualified health professionals who contractually agree to conduct qualified pediatric research are eligible to apply for this program.

Research and Development-Related Contracts

N 01 **Research and Development Contracts**
To develop and/or apply new knowledge or to test, screen, or evaluate a product, material, device, or component for use by the scientific community.

N 02 **Resource and Support Contracts - Awarded in the ICD**
To support intramural and extramural station support needs. This activity also includes the provision of resources to intramural research programs.

N 41 **Small Business Technology Transfer (STTR) Contracts - Phase I**
To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

N 42 **Small Business Technology Transfer (STTR) Contracts - Phase II**
To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

N 43 **Small Business Innovation Research (SBIR) Contracts- Phase I**
To support project, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s). These contracts may be made only with small businesses.

N 44 **Small Business Innovation Research (SBIR) Contracts - Phase II**
To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. These contracts may be made only to small businesses.

Research Program Projects and Centers

P 01 **Research Program Projects**
For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the

organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project

is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

P 20 **Exploratory Grants**

To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

P 30 **Center Core Grants**

To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. The core grant is integrated with the center's component projects or program projects, though funded independently from them. This support, by providing more accessible resources, is expected to assure a greater productivity than from the separate projects and program projects.

P 50 **Specialized Center**

To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes.

P 60 **Comprehensive Center**

To support a multipurpose unit designed to bring together into a common focus divergent but related facilities within a given community. It may be based in a university or may involve other locally available resources, such as hospitals, computer facilities, regional centers, and primate colonies. It may include specialized centers, program projects and projects as integral components. Regardless of the facilities available to a program, it usually includes the following objectives: to foster biomedical research and development at both the fundamental and clinical levels; to initiate and expand community education, screening, and counseling programs; and to educate medical and allied health professionals concerning the problems of diagnosis and treatment of a specific disease.

Research Projects

R 01 **Research Project**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

R 03 **Small Research Grants**
To provide research support specifically limited in time and amount for studies in categorical program areas. Small grants provide flexibility for initiating studies which are generally for preliminary short-term projects and are non-renewable.

R 13 **Conference**
To support recipient sponsored and directed international, national or regional meetings, conferences and workshops.

R 15 **Academic Research Enhancement Awards (AREA)**

To support small scale research projects conducted by faculty in primarily baccalaureate degree-granting domestic institutions. Awards are for up to $75,000 for direct costs (plus applicable indirect costs) for periods not to exceed 36 months.

R 18 **Research Demonstration and Dissemination Projects**
To provide support designed to develop, test, and evaluate health service activities, and to foster the application of existing knowledge for the control of categorical diseases.

R 21 **Exploratory/Developmental Grants**
To encourage the development of new research activities in categorical program areas. (Support generally is restricted in level of support and in time.)

R 24 **Resource-Related Research Projects**
To support research projects that will enhance the capability of resources to serve biomedical research.

R 25 **Education Projects**
For support to develop and/or implement a program as it relates to a category in one or more of the areas of education, information, training, technical assistance, coordination, or evaluation.

R 33 **Exploratory/Developmental Grants Phase II**
The R33 award is to provide a second phase for the support for innovative exploratory and development research activities initiated under the R21 mechanism. Although only R21 awardees are generally eligible to apply for R33 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under R33.

R 34 **Clinical Trial Planning Grant**
To provide support for the initial development of a clinical trial, including the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

R 37 **Method to Extend Research in Time (MERIT) Award**
To provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT award. Program staff and/or members of the cognizant National Advisory Council/Board will identify candidates for the MERIT award during the course of review of competing research grant applications prepared and submitted in accordance with regular PHS requirements.

R 41 **Small Business Technology Transfer (STTR) Grants - Phase I**
To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

R 42 **Small Business Technology Transfer (STTR) Grants - Phase II**
To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

R 43 **Small Business Innovation Research (SBIR) Grants - Phase I**
To support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s).

R 44 **Small Business Innovation Research (SBIR) Grants - Phase II**
To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. SBIR Phase II are considered ˜Fast-Track˜ and do not require National Council Review.

R 56 **High Priority, Short Term Project Award**
To provide limited interim research support based on the merit of a pending R01 application while applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Interim funded ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

RC1 **NIH Challenge Grants and Partnerships Program**
As part of the American Recovery and Reinvestment Act of 2009 (Recovery Act), NIH designated at least $200 million in FYs 2009 - 2010 for this new initiative to fund 200 or more grants, contingent upon the submission of a sufficient number of scientifically meritorious applications. The new program will support research that addresses specific scientific and health research challenges in biomedical and behavioral research that will benefit from significant 2-year jumpstart funds. In addition, Recovery Act funds allocated to NIH specifically for comparative effectiveness research (CER) may be available to support additional grants.

RC2 **High Impact Research and Research Infrastructure Programs**
To support high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could

support either a specific research question or propose the creation of a unique infrastructure/ resource designed to accelerate scientific progress in the future.

RC3 **Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Program**
To accelerate the transition of NIH-supported research innovations and technologies toward the development of products or services that will improve human health, through grants that may advance the mission of NIH and its Institutes and Centers (ICs), and create significant value and economic stimulus or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code is intended to support research and development (R&D) specifically targeted at activities that can help address the funding gap between promising R&D and transitioning to the market, often called the "Valley of Death" by contributing the critical funding needed by applicants to pursue the next appropriate milestone(s) toward ultimate commercialization; i.e., to carry out later stage research activities necessary to that end; to foster partnerships among a variety of research and development (R&D) collaborators working toward these aims. Awards are made only to U.S.-owned, for-profit enterprises doing a majority of its business in the United States. RC3 applications may be given funding priority if the applicant organization is associated with an enterprise that is of small size (e.g., 500 or fewer employees), and/or of limited resources, such as an early-stage company, and/or one positioned for receiving funding or in-kind support from a third-party investor and/or strategic partner. The RC3 SPAN program is not intended to support "upstream" R&D for doing feasibility testing of an innovative idea or to conduct early-stage R&D as an extension of such ideas. (Projects such as these should be submitted under the NIH SBIR/STTR programs.)

RC4 **High Impact Research and Research Infrastructure Programs—Multi-Yr Funding**
To support multi-year funded research with high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future. It is the multi-year funded companion activity code to the existing RC2; thus ICs need OER prior approval to use the RC4.

Research-Related Programs

S 06 **Minority Biomedical Research Support - MBRS**
To strengthen the biomedical research and research training capability of ethnic minority institutions, and thus establish a more favorable milieu for increasing the involvement of minority faculty and students in biomedical research.

SC 1 **Research Enhancement Award**
Individual investigator-imitated research projects aimed at developing researchers at minority-serving institutions (MSIs) to a stage where they can transition successfully to other s extramural support (R01 or equivalent).

SC 2 **Pilot Research Project**
Individual investigator-initiated pilot research projects for faculty at MSIs to generate preliminary data for a more ambitious research project.

SC 3 **Research Continuance Award**
Individual investigator-initiated research projects for faculty at MSIs to conduct research of limited scope in environments with limited research infrastructure/facilities.

Training Programs

T 32 **Institutional National Research Service Award**
To enable institutions to make National Research Service Awards to individuals selected by them for predoctoral and postdoctoral research training in specified shortage areas.

T 35 **NRSA Short-Term Research Training**
To provide individuals with research training during off-quarters or summer periods to encourage research careers and/or research in areas of national need.

T90 **Interdisciplinary Research Training Award**
To support comprehensive interdisciplinary research training programs at the undergraduate, predoctoral and/or postdoctoral levels, by capitalizing on the infrastructure of existing multidisciplinary and interdisciplinary research programs.

Cooperative Agreements

Note: For all funding mechanisms within this section, substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.

U 01 **Research Project--Cooperative Agreements**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

U 10 **Cooperative Clinical Research--Cooperative Agreements**
To support clinical evaluation of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between sponsoring institutions and participating principal investigators, and are usually conducted under established protocols.

U 13 **Conference--Cooperative Agreements**
To support international, national or regional meetings, conferences and workshops where substantial programmatic involvement is planned to assist the recipient.

U 19 **Research Program--Cooperative Agreements**
To support a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach. This generally involves the organized efforts of large groups, members of which are conducting research projects designed to elucidate the various aspects of a specific objective. Each project supported through this mechanism should contribute to or be directly related to the common theme of the total research effort. The award can provide support for certain basic shared resources, including clinical components, which facilitate the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence.

U 24 **Resource-Related Research Projects--Cooperative Agreements**
To support research projects contributing to improvement of the capability of resources to serve biomedical research.

U-32 **State-Based Diabetes Control Programs**
Programs in cooperation with State health agencies: To reduce the effect of preventable problems in service delivery to diabetics (such as excess days of hospitalization, high amputation rates, and the effect of insurance policy on securing care), to define the preventable service delivery problems, and to demonstrate improved service delivery to diabetics.

U 34 **Multi-Center Clinical Study Implementation Planning Grants**
Clinical Planning Grant Cooperative Agreement—To provide support, substantial Federal programmatic involvement, and technical assistance for the initial development of a clinical trial. Also, it would include the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

UC4 **High-Impact Research and Research Infrastructure Cooperative Agreements**
To support multi-year funded cooperataive agreement research with high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future. It is the cooperative agreement companion to the RCA. It is also the multi-year funded companion to the existing UC2; thus ICs need OER prior approval to use the UC 4.

UH3 **Exploratory/Developmental Cooperative Agreement Phase II**
To provide a second phase for the support for innovative exploratory and development research activities initiated under the UH2 mechanism. Although only UH2 awardees are generally eligible to apply for UH3 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under UH2.

UM- **Multi-Component Research Project Cooperative Agreements**
To support large-scale cooperative agreements involving complex clinical trials with multiple components (e.g., clinical networks). The components represent a variety of supporting functions and are not independent of the research projects. Substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award. The performance period may extend up to 7 years but only through the established deviation request process. ICs desiring to use this activity code for programs greater than 5 years must receive OPERA prior approval through the deviation request process.

X01 **Resource Access Program**
To invite eligible institutions to seek access to NIH research resources. This includes programs where institutions will request access to submit to the resource, e.g., high throughput screening assays. It also includes programs where access to a specific NIH research resource is needed to conduct certain research.

NIH Operates Under a Continuing Resolution

Notice Number:

NOT-OD-15-001

Key Dates

Release Date: October 1, 2014

Related Announcements

NOT-OD-14-055

Issued by

National Institutes of Health (NIH)

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under the Continuing Appropriations Act, 2015 (H.J.Res. 124) signed by President Obama on September 19, 2014. This Act (CR) continues government operations through December 11, 2014 at 99.9 percent of the FY 2014 enacted level.

Continuing the procedures identified under NOT-OD-14-055 and consistent with NIH practices during the CRs of FY 2006 – 2014, the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments to awarded levels will be considered after FY 2015 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2014 (see NOT-OD-14-053 and NOT-OD-14-046) remain in effect under this CR including the salary limitation set at Executive Level II of the Federal Pay Scale as described in NOT-OD-14-052.

Inquiries

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified on the Notice of Award.

NIH Fiscal Policy for Grant Awards – FY 2015 [example]

Notice Number: NOT-OD-15-050

Key Dates

Release Date: December 30, 2014

Related Announcements

NOT-OD-16-002

NOT-OD-15-048

NOT-OD-15-049

Issued by

National Institutes of Health (NIH)

Purpose

This Notice provides guidance about the NIH Fiscal Operations for FY 2015 and implements the Consolidated and Further Continuing Appropriations Act, 2015 (H.R. 83/Public Law 113-235), signed by President Obama on December 16, 2014. The Act provides NIH with $30.31 billion in new budget authority or equivalent (program level), an increase of approximately $240 million over the FY 2014 final budget allocations totaling $30.07 billion. The NIH will continue to manage its portfolio in biomedical research investments in a manner that includes recognizing applications from and providing special incentives for new investigators.

The following NIH fiscal policies are instituted in FY 2015:

FY 2015 Funding Levels: Non-competing continuation awards that have already been made in FY 2015 were generally funded at levels below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level) as described in NOT-OD-15-001. Such reductions may be fully or partially restored, depending on the Institute or Center. Non-competing continuation grants (research and non-research) including those that remain to be issued in FY 2015 likely will be made within the range between the commitment level indicated on the Notice of Award and 3 percent below that level. Out-year commitments for continuation awards in FY 2016 and beyond will remain unchanged. The NIH awarding Institutes/Centers (IC) will develop and post their fiscal policies consistent with overall NIH goals and available FY 2015 funds.

Ruth L. Kirschstein National Research Service Awards (NRSA): Consistent with the 2015 Consolidated and Further Continuing Appropriations Act and with the recommendations of the Advisory Committee to the Director regarding the Biomedical Research Workforce, the NIH will increase NRSA stipends by 2 percent on

average. The full range of stipend adjustments for FY 2015 is described at NOT-OD-15-048.

New Investigators: NIH will continue to support new investigators on R01 equivalent awards at success rates comparable to that of established investigators submitting new (Type 1) R01 equivalent applications. Achievement of comparable success rates should permit the NIH to support new investigators in accordance with the policies established in FY 2009 and subsequent years as described at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html and at http://grants.nih.gov/grants/new_investigators/index.htm.

Salary Limits: Section 203 of the 2015 Consolidated and Further Continuing Appropriations Act prohibits payments for salaries under grants and other extramural mechanisms in excess of Executive Level II currently set at $181,500. See NOT-OD-14-049 for additional information.

Other Legislative Mandates: Other statutory requirements will be described in a notice to be released early in January.

Additional Information: Additional details on Fiscal Operations, including specific funding strategies for ICs will be posted at http://grants.nih.gov/grants/financial/index.htm.

Inquiries

Questions about specific awards may be directed to the Grants Management Specialist identified in the Notice of Award.

2015 Award Funding Policy

The Department of Health and Human Services (HHS), including NIH is presently operating under a Continuing Resolution that continues government operations through December 11, 2014.

- Until FY 2015 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). See NOT-OD-15-001 for details.
- NIDDK will announce additional details regarding its interim FY 2015 funding policy, including details regarding funding of competing grant applications, once an NIH-wide policy has been announced.

2015 Award Funding Policy [example]

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports basic and clinical research on many of the most serious diseases affecting public health.

NIDDK extramural research is organized into 3 programmatic divisions:

1. Diabetes, Endocrinology, and Metabolic Diseases;
2. Digestive Diseases and Nutrition; and
3. Kidney, Urologic, and Hematologic Diseases.

The Institute supports basic and clinical research through investigator-initiated grants, program project and center grants, cooperative agreements, career development and training awards, and contracts.

Budget Data

Current Appropriation

NIH is operating at a program level of $30.31 billion in FY 2015, an increase of approximately $240 million over the FY 2014 final budget allocations.

NIDDK's discretionary appropriation for FY 2015 is $1.749 billion. This is an increase of about 0.02% from NIDDK's appropriation in FY 2014. This figure does not include the FY 2015 Special Type 1 Diabetes appropriation of $150 million that NIDDK oversees on behalf of NIH.

Funding Strategy

NIDDK is committed to supporting as many meritorious competing research grant applications as possible. Consistent with NIH policy (see NIH Guide Notice NOT-OD-15-050). NIDDK will manage its portfolio in biomedical research investments in a manner that includes recognizing applications from and providing special consideration for early career investigators.

To maximize our available resources, all grant awards will continue to be subject to programmatic adjustments from the NIDDK Advisory Council approved levels. These adjustments take into consideration the overall scientific and technical merit of the grant application, the cost of the proposed research, and other resources available for related research projects.

Funding Guidelines

Competing Awards

For FY 2015 NIDDK is establishing a nominal "payline" for new (Type 1) and renewal or competing continuation (Type 2) R01 applications of 13th percentile. Most R01 applications which have a primary assignment to NIDDK and which request less than $500,000 direct costs per year and score at or better than the 13th percentile will receive an award (applications which have NIDDK as a secondary assignment do not benefit from this payline). R01 applications requesting $500,000 or more in direct costs for any year will be held to a more stringent pay line – the 8th percentile for both Type 1 and 2 applications.

Please note the following regarding competing awards:

- NIDDK will exercise discretion and consider portfolio balance, programmatic importance and a number of other factors in determining precisely which applications are awarded.
- All grant awards will continue to be subject to programmatic adjustments from the NDDK Advisory Council approved levels.
- These funding levels are applicable for applications to be paid in FY 2015. Many applications submitted in FY 2015 (e.g., those submitted in January for September/October Advisory Council consideration) will not be eligible for funding consideration until FY 2016. The funding levels for FY 2016 cannot now be reliably predicted.

Early Stage Investigators (ESIs)

Fostering the success of investigators establishing careers in biomedical research is a high priority of the NIDDK and NIH. In FY 2015 NIDDK will place special emphasis on supporting ESIs (new investigators within 10-years of their terminal research degree or medical residency who have not yet been awarded a substantial, competing NIH research grant; see ESI FAQs) by establishing a nominal payline for R01 applications submitted by ESIs at the18th percentile. In addition, when possible and appropriate the full period of support recommended will be awarded.

R01s applications submitted by New Investigators who are not also ESIs will be paid up to the 13th percentile (same as the general pay line).

First Competitive Renewal of R01 Applications From Former NIDDK ESIs

NIDDK seeks to encourage the stable integration of early career researchers into the scientific research workforce. In support of this, the nominal payline for first competitive renewal applications for R01 awards to researchers who were ESIs when they competed for the initial NIDDK Type 1 R01

award will be 15th percentile in FY 2015. Only one award per eligible investigator may be considered for this special payline. If a special payline award is made to an eligible investigator any other eligible applications from that investigator will be considered for funding based on the standard nominal payline.

Bridge Support

In cases where a competing renewal application falls near but beyond the nominal payline, NIDDK will continue to consider interim support on a case-by-case basis and provide limited support in selected cases. The goal is to preserve essential research resources pending the re-review of a revised application. NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These awards provide support for investigators to collect preliminary data and use these data to revise and improve their R01 applications.

Duration of Grant Support

Competing awards are adjusted to achieve a 4-year average duration for research project grants. Nevertheless, applications from ESIs, MERIT extensions, program project grants, and clinical trial grants are generally awarded for the full length of their recommended project period.

Salaries

Section 203 of the 2015 External Link Disclaimer Consolidated and Further Continuing Appropriations Act prohibits payments for salaries under grants and other extramural mechanisms in excess of Executive Level II External Link Disclaimer currently set at $181,500. See NOT-OD-15-049 for additional information.

Non-competing (Continuation) Awards

Consistent with the NIH Fiscal Policy for Grant Awards – FY 2015 (see NOT-OD-15-050) non-competing (Type 5) continuation grants (research and non-research) including those that remain to be issued in FY 2015 will likely be made at the commitment level indicated on the Notice of Award (including those that were initially issued at 90% of the commitment level in FY 2015). Out-year commitments for continuation awards in FY 2016 and beyond remain unchanged.

Program Project (P01), Collaborative Interdisciplinary Team Science (R24) and Other Applications with Budgets Greater than $500K

NIDDK has adopted a more stringent funding practice for awarding program project (P01) grants, Collaborative Interdisciplinary Team Science (R24) and other investigator-initiated grant applications

with budgets of $500,000 or more requested direct costs in any one year. Prior approval is required before submitting an application for review that requests $500,000 or more in direct costs in any one year. The request to submit such applications should be received at least three months prior to the proposed submission date. Prior approval is required for renewal and revised applications as well as new applications. Please consult with the appropriate NIDDK program staff and visit the following site for information on research areas supported by NIDDK: http://www.niddk.nih.gov/research-funding/research-programs/Pages/default.aspx.

New (Type 1) and Renewal (competing continuation [Type 2]) program project (P01) applications may request a maximum of $6.25 million in direct costs over five years, excluding the Facilities & Administrative (F&A) costs for subcontracts. In addition to the caps on the amount requested, P01 awards are subject to administrative adjustment from the NIDDK Advisory Council approved levels. Also, please note that any P01 grant receiving a competing award in FY 2011 or later will be limited to one subsequent renewal.

Resources for New NIDDK Investigators

New investigators represent the future. They bring fresh ideas and technologies to research. NIDDK is dedicated to providing training and research funding for new investigators working on topics within its mission.

NIH Opportunities

NIH has policies and resources designed to assist new investigators in establishing their research programs and careers. New investigators should check the "New PI" box on the face page of their R01 applications so that they can be given special consideration. Peer reviewers are instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator. Institute staff pay special attention to applications from new investigators as well. In addition, NIH has piloted a program for rapid turnaround for new investigator applications allowing them to revise and resubmit more quickly.

NIDDK Opportunities

NIDDK has created a number of special new investigator opportunities and Frequently Asked Questions for new investigators. You are encouraged to discuss your ideas with NIDDK program staff as you are planning and preparing your grant application. Check NIDDK scientific areas of interest to find the right staff members and their contact information.

Differential payline – Fostering the success of investigators establishing careers in biomedical research is a high priority of the NIDDK and NIH. Each year, the NIDDK sets a nominal percentile "payline" for R01 applications based on available funds and the volume of applications. The payline for Early Stage Investigator (ESIs, New Investigators within 10 years of their terminal research degree or medical residency who have not yet been awarded a substantial, competing NIH research grant) R01 applications is five percentile points more generous than the regular payline for established investigators. While NIDDK often makes administrative reductions in grant duration, applications from ESIs that fall within the payline are usually awarded the full requested duration.

In addition, the nominal payline for the first competitive renewal applications for R01 awards to researchers who were ESIs when they competed for the initial NIDDK Type 1 R01 is two percentile points more generous than the regular payline. Only one award per eligible investigator may be considered for this special payline. If a special payline competitive renewal award is made to an eligible investigator, any other eligible application from that investigator will be considered for funding based on the standard nominal payline.

Second-level review – The NIDDK Advisory Council meets to provide second-level review after the initial round of peer review by Scientific Review Groups (study sections). All new investigator R01 applications within ten percentile points of the payline receive individual consideration during the second-level review process. This could result in the award of an R01 with a reduced budget or a smaller award such as an R56.

NIH High Priority, Short-Term Project Award (R56) – Although you cannot apply for this grant mechanism, NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These provide support for an investigator to collect preliminary data in order to submit an improved revised R01 application. During second-level review, new investigators are given special consideration for R56 awards.

Career Development (K) awards – NIDDK has a vigorous Career Award program.

Small grants (R03) awards – NIDDK has several relevant funding opportunities for small grants.

Mentoring workshops – NIDDK regularly holds workshops for recently funded new investigators.

Role of NIDDK Advisory Council

Established by law and charter, the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meets three times annually to advise the NIDDK about its research portfolio. The Council typically undertakes broad issues of science policy. An important role of the Council is to provide second-level peer review of grant applications that have been scored by scientific review groups. The Council members are an important liaison between the research communities they represent and NIDDK, which supports each community's research efforts.

Who are the Council members?

Members of the Advisory Council are drawn from the scientific and lay communities, are appointed for 4-year terms, and represent all areas within the Institute's research mission. The Council membership consists of 18 voting members, including 12 health or science experts and 6 public members.

Six nonvoting, *ex officio* members provide liaison with higher level agencies or organizations having missions consistent with that of NIDDK, including the Secretary, Department of Health and Human Services (DHHS), and representatives from the Department of Defense, Centers for Disease Control and Prevention, and Department of Veterans' Affairs.

Council's health or science experts contribute technical expertise and an understanding of the needs of the research communities of academia and industry. Council's public representatives impart a perspective of people affected by diseases in NIDDK's research mission.

Each Council member also belongs to one of the three Council subcommittees – Digestive Diseases and Nutrition; Diabetes, Endocrinology, and Metabolic Diseases; and, Kidney, Urologic and Hematologic Diseases, corresponding to NIDDK's extramural programmatic divisions.

A copy of the current Council roster is included in the next section on Advisory Council Logistical documents and online at http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/members/Pages/advisory-council-members.aspx

What does the Council do? **(For an abbreviated version see: "RESPONSIBILITIES OF NIDDK ADVISORY COUNCIL MEMBER" at the end of this book.)**

As required by law, chartered advisory committees, including the councils, are part of every NIH institute. NIDDK's Council performs the following four key roles:

- Conducts second-level peer review of grant applications scored by scientific review groups
- Advises NIDDK on broad issues of science policy
- Reviews NIDDK programs
- Clears concepts for Program Announcements (PAs), Requests for Applications (RFAs), and Requests for Proposals (RFPs).

The subcommittees conduct most of the NIDDK Division-specific other business, including the closed-session discussion of grant applications.

What is second-level review?

Second-level review is the assessment of the quality of the initial review of grant applications. The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote.

Expedited Concurrence of En Bloc Actions. For grant and cooperative agreement applications that have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution), excluding those from foreign organizations, a process of expedited concurrence is available. The purpose is to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive, and responsible manner. In this process, the power to review applications is delegated by the Chairman of the Advisory Council to specifically designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee consists of the Council Executive Secretary and six members of the NDDKAC. Two members are selected from each subcommittee of the NDDKAC. Electronic or written concurrence by a minimum of two members with no votes for nonconcurrence within 7 days of notification of posting is required for expedited concurrence approval.

For the first two Councils – January or February and May or June – expedited review enables NIDDK to fund grants a few weeks after the initial peer review meeting. Because September Council reviews applications for funding in the next fiscal year, applicants approved for funding through expedited review will get their awards after the Institute receives its next year's appropriation.

The NIDDK Director makes final funding decisions based on staff and Advisory Council/Board advice.

What happens at Council meetings?

Council meets in September, January or February, and May or June. Its activities are driven partly by the budget and appropriation cycle. For example, discussions in September reflect the beginning of the fiscal year.

In the morning, the full Council meets in open session to hear updates from the Director, NIDDK, and to discuss items that cut across NIDDK Divisional lines. This may include scientific and administrative topics for discussion, often presented by staff or outside speakers. ***Note: Open sessions are open to the public and members of the press may be present.***

In the early afternoon, the three subcommittees meet individually to review applications needing special consideration, discuss selective pay nominations, and recommend MERIT awards. Then, the Director, NIDDK, convenes the full Council for a short, closed meeting to discuss and formally approve subcommittee recommendations for funding grants.

Note: A sample agenda is included in the on Advisory Council Logistical documents. The next meeting's agenda is posted several weeks before each meeting and is available from the Council's home page (http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/Pages/advisory-council.aspx). Minutes are also posted and available from the home page.

What is Council’s role in concept clearance?

NIDDK seeks Council's advice for long-term planning at an early stage. However, the decision to go forward with an initiative is made by NIDDK, based on scientific and programmatic priorities and on the availability of funds.

Definitions of Special Issues Presented to Council

Program staff must prepare the following types of special issues to present to Council.

1. **Reinstatement of Research Aims**. Applications for which the division is requesting to reinstate specific aims or research not recommended for support by the study section.

2. **Non-Peer-Reviewed Applications**. Used in some circumstances. Council performs both initial peer review and second-level review functions. Renewal MERIT awards are the most common example.

3. **Deferred Applications**. All Council-deferred applications independent of review results.

4. **Unresolved Appeals.** Formerly called rebuttals. When program staff working with a scientific review officer have been unable to resolve the applicant's concerns, the DEA director reviews the appeal, and staff present it to Council.

5. **Foreign Applications**. Foreign applications a division proposes to award. (Foreign applicants may NOT receive R56-Bridge awards.)

6. **Council Member Applications**. Applications proposed for award where a Council member is PI. A subcommittee other than the one on which the Council member serves reviews these applications.

7. **Human Subjects**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of human subjects.

8. **Biohazards**. Applications proposed for award with unresolved concerns about biohazards.

9. **Use of Animals in Research**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of animals in research.

10. **Minority Recruitment Plans in Institutional Training Grant Applications**. Fundable, meritorious National Research Service Award applications with inadequate plans for minority recruitment. When the study section deems a plan inadequate, options are (1) no special action, pay by priority score; (2) defer payment pending submission and staff approval of a recruitment plan; or (3) defer for study section re-review pending receipt of an acceptable plan.

11. **Inclusion of Women and Minorities as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

12. **Inclusion of Children as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

13. **Special Council Review**. Review of research applications from Program Investigator with more than $1,000,000 in direct costs in annual NIH support.

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

AUTHORITY

42 U.S.C. 284a, sections 406 and [479] of the Public Health Service (PHS) Act, as amended, The National Diabetes and Digestive and Kidney Diseases Advisory Council (Council) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary) and the Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK, also referred to as Institute) on matters related to the activities carried out by and through the Institute and the policies respecting these activities.

DESCRIPTION OF DUTIES

The Council may recommend to the Secretary, in accordance with section 231 of the PHS Act, as amended, acceptance of conditional gifts for study, investigation, or research on basic and clinical diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Institute.

The Council may review applications for grants and cooperative agreements for research and training and recommend approval of applications for projects which show promise of making valuable contributions to human knowledge; may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute; may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country and, with the approval of the Director of NIDDK, make available such information through appropriate publications for the benefit of public and private health entities, health professions personnel and scientists, and for the information of the general public.

The Council may prepare, for inclusion in the Biennial Report prepared by the Director, National Institutes of Health (NIH), under section 403 of the PHS Act, as amended (1) comments reflecting the activities of the Council in the fiscal years in which the report is prepared; (2) comments on the progress of the Institute in meeting its objectives; and (3) recommendations respecting the future directions and program and policy emphasis of the Institute.

AGENCY OR OFFICIAL TO WHOM TOHE COMMITTEE REPORTS

The Council will advise the Secretary; the Assistant Secretary for Health; the Director, NIH; and the Director, NIDDK.

SUPPORT

Management and support services will be provided by the Division of Extramural Activities,

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is $93,758. The estimated annual person-years of staff support required is 0.3, at an estimated annual cost of $49,807.

DESIGNATED FEDERAL OFFICER

The Director, NIDDK, will assign a full-time or permanent part-time NIDDK employee to serve as the Designated Federal Officer (DFO) of the Council. In the event that the DFO cannot fulfill the assigned duties of the Council, one or more full-time or permanent part-time NIDDK employees will be assigned these duties on a temporary basis.

The DFO will approve or call all of the Council's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Council and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH, or Director, NIDDK.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Council will be held not less than three times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Council's functions, dates and places of meetings, and a summary of the Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Continuing. This Council is mandated by statute with no specified end date.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the Charter for the National Diabetes and Digestive and Kidney Diseases Advisory Council will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Council will consist of 18 members appointed by the Secretary and 6 nonvoting ex officio members: the Secretary; the Director, NIH; the Director, NIDDK; the Chief Medical Director of the Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs; and the Assistant Secretary for Science and Education, United States Department of Agriculture (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its functions. Of the 18 appointed members, 12 will be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the NIDDK, particularly representatives of the health and scientific disciplines in the areas of diabetes mellitus, endocrinology, metabolism, digestive diseases, nutrition, nephrology, urology, hematology and public health. Six of the members will be appointed by the Secretary from the general public and will include leaders in the fields of public policy, law, health policy, economics, and management. All non-Federal members will serve as Special Government Employees. A member who has been appointed for a term of four years may not be reappointed to this Council before two years from the date of expiration of that member's term of office. A quorum for the conduct of business by the full Council will consist of a majority of currently appointed members.

Members will be invited to serve for overlapping four-year terms, except that any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

The Chair of the Council will be selected by the Secretary from among the appointed members, except that the Secretary may select the Director, NIDDK, to be the Chair. The term of office of the Chair will be two years.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Council's jurisdiction. The advice/recommendations of a subcommittee /working group must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. A quorum for a subcommittee will be three members. Ad hoc consultants do not count towards the quorum and may not vote. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the Council and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Department policies. Council and subcommittee records will be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE

October 31, 2012

APPROVED

9-15-12
Date

Director, NIH

NOTICE OF RECHARTER

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES
ADVISORY COUNCIL

The Council was established by statute and has functions which are of a continuing nature so that its duration is not governed by section 14(a) of the Federal Advisory Committee Act but is otherwise provided for by law. The Council is hereby rechartered in accordance with section 14(b)(2) of that Act.

5-15-12
Date

Francis V. Collins
Director, NIH

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides access to NIH summary statements. Using World Wide Web and Internet capabilities for database search and retrieval, as an NIDDK Advisory Council member you may read, search, sort, and print any or all of the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB each night, so the ECB is always current.

> ***The data in the ECB, and the codes you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it unattended. Use it and then disconnect. If for some reason you are inactive for approximately one hour, the system will automatically disconnect, and you will have to login again.***

How do I get started?
You or your institution will supply your computer access to the NIH computer, via an Internet connection and a WEB browser (such as Firefox, Netscape Navigator, or Internet Explorer). An NIDDK staff member will give you the information necessary to identify yourself to the NIH computer where the ECB is located. That information includes two codes. The first is called your "USER NAME," the second is your "PASSWORD." Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page**:**
https://ecb.nih.gov/council/login.cfm

You will see a screen entitled "**NIH Electronic Council Book**" with two blank boxes for your USER NAME and your PASSWORD. Neither the USER NAME nor the PASSWORD are case sensitive. To log in to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can login to the ECB. To change your password, go to the ECB login page (see below) and click on the link to the "Council Member Change Password Page." Use the NIDDK-issued password as the "Old Password," and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please contact Teresa Lindquist (lindquit@niddk.nih.gov, 301-451-6418).

If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?
When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the "Back" button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option.** There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI's institution.

The Resume Project List retrieves the "Summary of Review and Discussion" section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either "Primary and Dual Projects" or "Dual Projects only" in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator's name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator's last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic,** simply enter the appropriate term in the boxes labeled "Summary Text Contains." This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND, OR*, and *NOT*) to connect two character strings. Note: If one is searching for a topic such as "endocrine disruptors" consider the two words as a single character string and enter both words in the left box separated by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principle Investigator Starts With:" For example, searching for "**Ham"** will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP)**, place **NBH** in the first three boxes. Leave the next box blank and enter OBSP in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

1 New
2 Competing Continuation
3 Supplement
4 Extension

5 Noncompeting Continuation
6 Change of Institute or Division
7 Change of Grantee or Training Institution
8 Change of Institute or Division (noncompeting continuation)
9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).

- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.

- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.

- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND, OR, NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the “Clear Scores” button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2008, the entry would be 01/15/2008 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting "Greater Than or Equal To" from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box 'Foreign Grants' to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 100 to 300 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer's email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note**: Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available.

Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a “Zip” file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:
Theresa Smith, smiththe@niddk.nih.gov or 301-443-9908.

National Diabetes and Digestive and Kidney Diseases Advisory Council: Advisory Council Operating Procedures

(Pending Approval of NDDKAC)

February 2015
Expiration: February 2016

A. Purpose

This documents operating procedures established annually by the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) for use of council-delegated authorities. These authorities establish program management and council review procedures for the Institute's extramural programs and establish authorities for management actions undertaken by staff.

In general, the Council makes three types of recommendations relating to second level review of scientific review group (SRG) actions: (1) the Council can concur with the SRG critique; (2) it can suggest a different budget and/or a different length of the grant period; and (3) it can advise deferral of an application for re-review. Specific procedures are given below for each of these types of actions. These procedures are meant to ensure a level of uniformity and comparability across the Council's three subcommittees, which are aligned with the Institute's programmatic divisions. Those subcommittees of Council are free to develop and utilize their own procedures with the understanding that they be consistent with the operating procedures.

B. Background

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and other National Institutes of Health (NIH) awarding Institutes are required by policy to establish procedures for interactions between Advisory Councils and the staff responsible for the day-to-day management of extramural portfolios. These procedures, referred to as Council-delegated authorities, govern staff and NDDKAC responsibilities with regard to grant portfolio management.

C. Definitions

1) Council Delegated Authorities: Those actions negotiated between the NDDKAC and the Director, NIDDK that govern management of the Institute's extramural program portfolio.

2) En Bloc Action: An action taken by Council on a group of applications under review rather than on specific individual applications being presented to NDDKAC for review.

3) Staff Actions: Actions that, based on policy and procedures, do not require a specific action on the part of the NDDKAC. These actions include, but may not necessarily be limited to: (a) change of grantee institution, (b) change of principal investigator, (c) administrative supplements, (d) no-cost extensions, and (e) phase-out or interim support.

4) Communication Letter: A communication between an applicant and Institute staff that is included for NDDKAC information purposes. Communication letters may or may not be acted upon by Council and need not be brought up for special discussion.

D. Policy and Implementation Procedures

The NDDKAC by approval has delegated authority to the NIDDK Director for staff to negotiate adjustments in dollars and/or the terms and conditions of grant and cooperative agreement awards recommended by the Council. In general, these operational guidelines for administrative actions are

developed to provide a day-to-day framework for the smooth and effective operations necessary after review of grant applications by the Council. They are principally intended to enhance the administration of the federal assistance portfolio by the NIDDK.

NIDDK program and grants management staff analyze and review applications, i.e., noncompeting continuation applications and competing applications (new, resubmission (amended) renewal, or revision (supplemental) before issuing a grant award. NIDDK staff negotiates appropriate adjustments, when applicable, for such changes as the base used for recovery of facilities and administrative costs and/or legislatively imposed salary or other limits. Also, staff can make adjustments to reconcile inconsistencies between SRG recommended budgets and approved activities.

Administrative requests for increases in direct costs, which are the result of marked expansion or significant change in scientific content after formal peer review, will be referred to the Council for advice and recommendation. The NIDDK Director will determine whether the urgency is sufficient to warrant interim consultation with the Council by mail, e-mail, facsimile or telephone, instead of delaying action until the next Council meeting, or by mutual agreement, in rare instances the NIDDK Director may act on behalf of the Council as a whole.

Actions not requiring NDDKAC review or advice are: (1) change of grantee institution, (2) change of principal investigator, (3) administrative supplements to provide additional support either to meet the increased cost of maintaining the level of research previously recommended, or to accommodate activities or to meet needs judged by staff to be within the scope of the previously peer reviewed project, or (4) phase-out or interim support. The Council will be provided with notice of general solicitations for administrative supplements if they apply to an entire class of applications. In addition, NIDDK staff may restore requested time and support which were deleted by the initial review group when the principal investigator has provided justification in a communication letter, and the restoration is in the best interest of the Institute and the project is of high programmatic relevance. Staff will record the action taken and its justification in a memo to the file. In addition, restorations will be summarized for Council information at the next regular scheduled meeting.

Each Council round Council will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under NIH policy. For each application on the list that may actually be funded, NIDDK staff will provide information about the other funding for the PI that brings his/her direct cost total to the $1 million threshold and a justification for considering funding. Council members will review these cases and indicate whether or not they have concerns.

NIH, in an effort to improve the efficiency of making awards, authorized the use of an expedited en bloc concurrence Council review process. NIDDK makes use of an expedited concurrence of en bloc actions to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive and responsible manner.

All grant and cooperative agreement applications, excluding those from foreign organizations, which have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution) or need SCR, will follow a process of expedited concurrence whereby the review of applications is delegated by the Chairman of the Advisory Council to designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee shall consist of the Council Executive Secretary (non-voting) and six members of the NDDK Advisory Council. Two members will be selected from each subcommittee of the NDDK Advisory Council.

The Executive Secretary will alert the concurrence committee members with responsibility for expedited concurrence when review outcomes for eligible applications are available in the Electronic Council Book. The Electronic Council Book enables members to access: Application Number, Principal Investigator, Project Title and Percentile/Priority Score. Typically this will occur once each Council round, several weeks before the scheduled NDDKAC meeting, however circumstances may arise that will require an additional, earlier expedited concurrence review to allow a set of applications to be funded in a timely manner to optimize the initiation or continuation of the proposed research. In the event of an earlier expedited concurrence review the same procedures described below will be followed including the involvement of the full NDDKAC.

Electronic or written concurrence by a minimum of two members with no votes for non-concurrence within seven days of notification of posting is required for expedited concurrence approval. Any member may bring an application to full NDDKAC consideration without the need for justification. Any single vote for non-concurrence within the allotted time period will result in that application going for regular consideration to the NDDKAC under its normal procedures for concurrence. Members not acting upon an application within the allotted time period after posting will be considered to have abstained from a vote on that application. Expedited listings lacking enough votes for final action will be presented to the regular NDDKAC meeting for review.

The full NDDKAC will be provided with a list of all applications eligible for expedited concurrence, as well as the outcome of the vote by the concurrence committee members on those applications. The Executive Secretary will report the expedited concurrence recommendations during the closed session of the full Advisory Council meeting when reviewed applications are discussed.

The NDDKAC also advises the Institute on: The adequacy of the initial review process, including appeals to grant application review; nominations for and extensions of, Method to Extend Research in Time (MERIT) awards; and, funding of applications with Special Emphasis dollars. Finally, the NDDKAC will receive a report annually on the activities of the NIDDK Board of Scientific Counselors.

E. Exceptional Situations
As circumstances require, based on programmatic considerations, the Director, NIDDK after consultation with Council, may make exceptions to these guidelines.

Exceptions to these procedures should be extremely rare because there needs to be consistent application of these procedures across extramural divisions. Nonetheless, circumstances may require the deviation from the prescribed procedure in order to achieve the mission of the NIDDK. By NDDKAC delegated procedures, the Director, NIDDK has authority to act upon unusual or extenuating circumstances. These actions are usually discussed by a subset of Council members selected by the Director and Executive Secretary of NDDKAC. Any actions of this exceptional nature must be appropriately documented as necessary for the official record, and should be reported to Council at its next scheduled meeting.

F. References
1) Public Health Service Act as amended, 42 USC 52h, 42 USC 241, 42 USC 284a

2) NIH Manual Chapter 1805, Use of Advisors in Program and Project Review and Management (http://www1.od.nih.gov/oma/manualchapters/management/1805/)

3) NIH Manual Chapter 1810-1, Procedures for Avoiding Conflict of Interest for NIH Special Government Employee SGE Advisory Committee Members (http://www1.od.nih.gov/oma/manualchapters/management/1810-1/)

4) NIH Manual Chapter 3005, Review and Evaluation of Intramural Programs (http://www1.od.nih.gov/oma/manualchapters/intramural/3005/)

5) NIH Manual Chapter 4204-204B, Peer Review Process (http://oma.od.nih.gov/manualchapters/grants/4204-204B/)

6) NIH Manual Chapter 54104, NIH Research Grants Involving Foreign Institutions and International Organizations (http://oma.od.nih.gov/manualchapters/grants/54104/)

7) NIH Manual Chapter 54206, Responsibility for Care and Use of Animals (http://oma.od.nih.gov/manualchapters/contracts/6380-2/)

8) NIH Manual Chapter 54513, Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities (http://oma.od.nih.gov/manualchapters/grants/54513/)

9) NIH Manual Chapter 7410, Review and Documentation of Protections for Human Subjects in Grant Applications and Contract Proposals (http://oma.od.nih.gov/manualchapters/comgc/7410/)

10) OER Policy & Guidance: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects – Policy Implementation Page (http://grants.nih.gov/grants/funding/women_min/women_min.htm)

11) OER Policy & Guidance: Inclusion of Children Policy Implementation (http://grants.nih.gov/grants/funding/children/children.htm)

12) NOT-OD-12-140: Notice of Special Council Review of Research Applications from PDs/PIs with More than $1.0 Million Direct Costs in Annual NIH Support (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html)

12/3/15

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL
(All terms end October 31)

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National Institutes of Health
Department of Health and Human Services

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NIDDK Advisory Council Meetings Dates: 2016 - 2017

2016

January 27-28 (Wednesday and Thursday)
May 18-19 (Wednesday and Thursday)
September 7-8 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7

2017

February 1-2 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7
May 10-11 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7
September 6-7 (Wednesday and Thursday)
Natcher Conference Center (Building 45) Conference Rooms E1/E2, D and F1/F2

200th Meeting of the
NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

Building 31, C Wing, 6th Floor, Conference Room 10

January 27, 2016

OPEN SESSION 8:30 a.m. to 12:00 noon

I. CALL TO ORDER — **Dr. Rodgers**

II. CONSIDERATION OF SUMMARY MINUTES OF THE 199th COUNCIL MEETING — **Dr. Rodgers**

III. FUTURE COUNCIL DATES — **Dr. Rodgers**

2016

May 18-19 (Wednesday and Thursday)
September 7-8 (Wednesday and Thursday)
All meetings in 2016 will be held in Building 31, Conference Rooms 10, 6 and 7

2017

February 1-2 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7
May 10-11 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7
September 6-7 (Wednesday and Thursday)
Natcher Conference Center (Building 45)
Conference Rooms E1/E2, D and F1/F2

IV. ANNOUNCEMENTS
Confidentiality/Conflict of Interest — **Dr. Stanfield**

V. REPORT FROM THE NIDDK DIRECTOR — **Dr. Rodgers**

VI. UPDATE FROM THE DIRECTOR, NATIONAL INSTITUTE OF MINORITY HEALTH DISPARITIES (NIMHD) — **Dr. Pérez-Stable**

VII. COFFEE BREAK 10:15 a.m.

VIII. UPDATE FROM THE DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS) **Dr. Koroshetz**

IX. SCIENTIFIC PRESENTATION: **Dr. Bonventre**
The Kidney Repair Shop

X. SUBCOMMITTEE MEETINGS

1:00 to 4:00 p.m.

Diabetes, Endocrinology, and Metabolic Diseases
Building 31, C Wing 6th Floor Conference Center, Room 10
Closed Session: 1:00 p.m. – 2:00 p.m.
Open Session: 2:00 p.m. – 4:00 p.m.

Digestive Diseases and Nutrition
Building 31, C Wing 6th Floor Conference Center, Room 6
Open Session: 1:00 p.m. – 2:30 p.m.
Closed Session: 2:30 p.m. – 4:00 p.m.

Kidney, Urologic, and Hematologic Diseases
Building 31, C Wing 6th Floor Conference Center, Room 7
Open Session: 1:00 p.m. – 3:00 p.m.
Closed Session: 3:00 p.m. – 4:00 p.m.

CLOSED SESSION 4:15 p.m. to 4:30 p.m.

XI. REPORTS OF SUBCOMMITTEES: CONSIDERATION OF APPLICATIONS **Dr. Stanfield**

Diabetes, Endocrinology, and Metabolic Diseases
Digestive Diseases and Nutrition
Kidney, Urologic, and Hematologic Diseases

XII. ADJOURNMENT **Dr. Rodgers**

Meeting Minutes
National Diabetes and Digestive and Kidney Diseases
Advisory Council
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Department of Health and Human Services

I. CALL TO ORDER
Dr. Rodgers

The NIDDK Director, Dr. Griffin P. Rodgers, called to order the 197th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m. on May 13, 2015, in Building 31 of the NIH campus, Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Sharon Anderson
Dr. Gopal Badlani
Dr. Joseph Bonventre
Dr. David Brenner
Dr. Eugene Chang
Dr. Mark Donowitz
Dr. Lee Kaplan
Dr. Kenneth Kaushansky
Dr. David Klurfeld
Ms. Ellen Leake
Dr. Jerry Palmer
Dr. Craig Peters
Dr. Alan Saltiel
Dr. Jean Schaffer
Dr. Alan Shuldiner
Dr. Irving Smokler
Dr. Bruce Spiegelman
Ms. Pamela Taylor
Dr. Robert Vigersky

Also Present:
Dr. Griffin Rodgers, Director, NIDDK
Dr. Gregory Germino, Deputy Director, NIDDK
Dr. Brent Stanfield, Executive Secretary, NIDDK Advisory Council

B. NIDDK STAFF AND GUESTS

Abbott, Kevin – NIDDK
Abraham, Kristin – NIDDK
Agodoa, Lawrence – NIDDK
Akolkar, Beena – NIDDK
Andersen, Dana – NIDDK
Arreaza, Guillermo – NIDDK
Barnard, Michele – NIDDK
Bavendam, Tamara – NIDDK
Begum, Najma – NIDDK
Best, Carolyn – American Urol. Assoc.
Bleasdale, John – CSR
Blondel, Olivier – NIDDK
Bourque, Sharon – NIDDK
Bremer, Andrew – NIDDK
Buchanan, Sarah – NEFCARE
Calvo, Francisco – NIDDK
Camp, Dianne – NIDDK
Carrington, Jill – NIDDK
Cerio, Rebecca – NIDDK
Cheng, Clara – CSR
Chen, Hui – CSR
Cho, Jennifer – NIDDK
Choporis, Louis – NIDDK
Chowdhury, Bratati – NIDDK
Copeland, Randy – NIDDK
Cowie, Catherine – NIDDK
Curtis, Leslie – NIDDK
Dayal, Sandeep – NIDDK

Densmore, Christine – NIDDK
Dirks, Dale – NEFCARE
Doherty, Dee – NIDDK
Donohue, Patrick – NIDDK
Doo, Ed – NIDDK
Drew, Devon – NIDDK
Duggan, Emily – NIDDK
Evans, Mary – NIDDK
Farishian, Richard – NIDDK
Feld, Carol – NIDDK
Flessner, Michael – NIDDK
Fonville, Olaf – NIDDK
Fradkin, Judith – NIDDK
Gallivan, Joanne – NIDDK
Gansheroff, Lisa – NIDDK
Goter-Robinson, Carol – NIDDK
Guo, Xiaodu – NIDDK
Haft, Carol – NIDDK
Hall, Sherry – NIDDK
Hamilton, Frank – NIDDK
Hoff, Eleanor – NIDDK
Hoffert, Jason – NIDDK
Hoofnagle, Jay – NIDDK
Hoover, Camille – NIDDK
Hoshizaki Deborah – NIDDK
Ivins, Jonathan – CSR
Jerkins, Connie – NIDDK
Stephen, James – NIDDK
Jones, Teresa – NIDDK
Karp, Robert – NIDDK
Karimbakas, Joanne – NIDDK
Ketchum, Christian – NIDDK
Kimmel, Paul – NIDDK
Kirkali, Ziya – NIDDK
Kranzfelder, Kathy – NIDDK
Kuaban, Alice – Amer. Soc. Heme.
Kuczmarski, Robert – NIDDK
Laakso, Joseph – Endocrine Society
Laughlin, Marin – NIDDK
Leschek, Ellen – NIDDK
Li, Yan – NIDDK
Linder, Barbara – NIDDK
Malik, Karl – NIDDK
Malozowski, Saul – NIDDK
Maruvada, Padma – NIDDK
Margolis, Ronald – NIDDK
Martey, Louis – NIDDK
McBryde, Kevin – NIDDK
Menke, Andy – Social and Sci. Systems
Miller, David – NIDDK
Moxey-Mims Marva – NIDDK
Mullins, Christopher – NIDDK
Mullsteff, Clairisse – NIDDK
Narva, Andrew – NIDDK
Nguyen, Van – NIDDK
Nurik, Jody – NIDDK
Olan, Grant – Amer. Soc. Neph.
Olumi, Aria – Mass. Gen. Hosp.
Pawlyk, Aaron – NIDDK
Perrin, Peter – NIDDK
Perry-Jones, Aretina – NIDDK
Pike, Robert – NIDDK
Pileggi, Antonello – CSR
Podskalny, Judith – NIDDK
Ramani, Rathna – NIDDK
Rankin, Tracy – NIDDK
Rasooly, Rebekah – NIDDK
Reiter, Amy – NIDDK
Riber, Morgan – NIDDK
Rivers, Robert – NIDDK
Roberts, Tibor – NIDDK
Rosenberg, Mary Kay – NIDDK
Rosendorf, Marilyn – NIDDK
Roy, Cindy – NIDDK
Ruhl, Constance –Social and Sci. Systems
Rushing, Paul – NIDDK
Rys-Sikora, Krystyna – NIDDK
Saslowsky, David – Boston Child. Hosp.
Sato, Sheryl – NIDDK
Savage, Peter – NIDDK
Sechi, Salvatore – NIDDK
Serrano, Jose – NIDDK
Sheets, Dana – NIDDK
Shelness, Gregory – CSR
Sherker, Averell – NIDDK
Shepherd, Aliecia – NIDDK
Sierra-Rivera, Elaine – CSR
Silva, Corinne – NIDDK
Singh, Megan – NIDDK
Smith, Philip – NIDDK
Spain, Lisa – NIDDK
Star, Robert – NIDDK
Stoeckel, Luke – NIDDK
Tuncer, Diane – NIDDK
Tatham, Thomas – NIDDK
Teff, Karen – NIDDK
Tilghman, Robert – NIDDK
Torrance, Rebecca – NIDDK
Unalp-Arida, Aynur – NIDDK
Van Raaphorst, Rebekah – NIDDK
Wellner, Robert – NIDDK
Wilkerson, Anita – NIDDK
Woynarowska, Barbara – NIDDK
Wright, Elizabeth – NIDDK
Yang, Jian – NIDDK
Yanovski, Susan – NIDDK

C. ANNOUNCEMENTS
Dr. Rodgers and Dr. Germino

In Memoriam

Dr. William D. Steers, a former NIDDK Council member, passed away in April 2015. He had served on the Kidney, Urologic, and Hematologic Diseases (KUH) Subcouncil. Dr. Steers was Professor and Chairman of the Department of Urology at the University of Virginia Health System, and Editor of *The Journal of Urology.* He was a faculty member at the University of Virginia since 1988, became Chair of the Department of Urology in 1995, and was awarded the Hovey Dabney Professorship in 2003. With more than 300 basic research and clinical publications, his diverse clinical interests spanned urinary incontinence, benign prostatic hyperplasia, neurogenic bladder and robotic surgery for prostate cancer. In addition to serving on the NIDDK Advisory Council, he had been a member of the FDA's Reproductive Medicine Advisory Panel. He also chaired the NIH's Urinary Incontinence and Interstitial Cystitis Clinical Trials. He was a Principal Investigator on the original clinical trials on the use of Viagra for erectile dysfunction. Among his many honors for contributions to urology, Dr. Steers received the American Urological Association's (AUA) Gold Cystoscope Award in 1994 and the Hugh Hampton Young Award in 2011. He was also selected to receive a Presidential Citation in May 2015 for years of service to the AUA.

Dr. Russell Chesney, a long-serving Chair of the Department of Pediatrics at the University of Tennessee Health Science Center and a pediatric nephrologist at Le Bonheur Children's Hospital, passed away in April 2015. Among his many research endeavors, Dr. Chesney chaired the Steering Committee of the NIDDK-funded Randomized Intervention for Children with Vesicoureteral Reflux (RIVUR) trial, and was a leader of the Pediatric Pharmacology Research Unit, funded by the NIH's *Eunice Kennedy Schriver* National Institute of Child Health and Human Development. He also served as President of the American Pediatric Society and Chairman of the American Board of Pediatrics. Dr. Chesney was a committed physician to children and mentor to trainees and colleagues alike.

NIDDK Staff

Dr. Wei Yang, Senior Investigator in the NIDDK Intramural Laboratory of Molecular Biology, was elected to the American Academy of Arts and Sciences. Founded in 1780, the Academy is one of the nation's most prestigious honorary societies. Current membership includes more than 250 Nobel laureates and more than 60 Pulitzer Prize winners. In a recent *Nature* paper, Dr. Yang and her team reported the crystal structure of the RAG1-RAG2 protein complex, which initiates DNA rearrangement to generate millions of antibodies and T-cell receptors that defend against infection.

Dr. Judith Podskalny is retiring from the NIDDK after more than 40 years of service. Dr. Podskalny made major contributions as Program Director for the Career Development and Research Fellowship programs in the Division of Digestive Diseases and Nutrition (DDN). She was also responsible for trans-NIDDK medical student training, involving both short-term training of medical students, and the Medical Student Research Training Program. In addition, Dr. Podskalny served as a Program Director for the Digestive Diseases Centers Programs. She is widely recognized both at NIH and in the extramural community as an extraordinarily dedicated and talented administrator.

Samuel J. Heyman Service to America Medals

Dr. Germino announced that Dr. Rodgers has been honored as a Finalist in the 2015 Samuel J. Heyman "Service to America Medals" – often called the "Sammies." These prestigious awards are presented annually by the nonprofit, nonpartisan Partnership for Public Service to celebrate excellence in the federal civil service. Awards will be announced this Fall. Dr. Rodgers' nomination is based on his research in sickle cell disease. He and colleagues developed the first effective drug treatment--hydroxyurea--for sickle cell disease. This treatment has decreased the need for blood transfusions and lessened pain and suffering for patients. He has also collaborated on a stem cell transplant clinical trial reported last year, which reversed the illness in a majority of patients.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 197th COUNCIL MEETING

Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the **197th** Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES

Dr. Rodgers

Dr. Rodgers reminded the Council of upcoming Council dates. Most meetings are expected to be a single day. However, Council members were asked to hold both days to ensure flexibility should a situation arise where a longer meeting is required.

2015
September 9-10 (Wednesday and Thursday)

2016
January 27-28 (Wednesday and Thursday)
May 18-19 (Wednesday and Thursday)
September 7-8 (Wednesday and Thursday)

2017
February 1-2 (Wednesday and Thursday)
May 10-11 (Wednesday and Thursday)
September 6-7 (Wednesday and Thursday)

III. ANNOUNCEMENTS
Dr. Stanfield

Confidentiality

Council members were reminded that material furnished for review purposes and discussion during the closed portion of the meeting is considered confidential. The content of discussions taking place during the closed session may be disclosed only by the staff and only under appropriate circumstances. Any communication from investigators to Council members regarding actions on an application must be referred to the Institute. Any attempts by Council members to handle questions from applicants could create difficult or embarrassing situations for the members, the Institute, and/or the investigators.

Conflict of Interest

Dr. Stanfield reminded the Council that advisors and consultants serving as members of public advisory committees, such as the NIDDK National Advisory Council, may not participate in situations in which any violation of conflict of interest laws and regulations may occur. Responsible NIDDK staff shall assist Council members to help ensure that a member does not participate in, and is not present during, the review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, partner (including close professional associates), or an organization with which the member is connected.

To ensure that a Council member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file. Dr. Stanfield noted that each Council member's folder contained a statement regarding conflict of interest in his or her review of applications. He said that each Council member should read it carefully, sign it, and return it to the NIDDK before leaving the meeting.

Dr. Stanfield said that, at Council meetings when applications are reviewed in groups without discussion, that is, "en bloc" action, all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict.

With respect to multi-campus institutions of higher education, Dr. Stanfield said that: An employee may participate in any particular matter affecting one campus of a multi-campus institution of higher education if the employee's financial interest is solely employment in a position at a separate campus of the same multi-campus institution, and the employee has no multi-campus responsibilities.

IV. REPORT FROM THE NIDDK DIRECTOR
Dr. Rodgers

FY 2015 Operating Budget

Dr. Rodgers reminded the Council that the NIDDK is currently operating on its FY 2015 budget, which provides a 0.8 percent increase over the preceding fiscal year. This is an increase of about $15 million, which includes mandatory funds for the Special Statutory Funding Program for Type 1 Diabetes Research.

FY 2016 President's Budget Request

On February 2, 2015, the President submitted his Fiscal Year 2016 budget request for federal agencies. His budget calls for a $1 billion increase for NIH, of which an increase of $39 million is requested for the NIDDK. These amounts include the special funds for type 1 diabetes research. The President's budget proposes to eliminate sequestration and to use other alternatives to reduce spending over the next decade.

The House and Senate held hearings on the President's budget for the NIH on March 3 and April 30, respectively. Both hearings went well, with Members of Congress expressing strong support for NIH budget increases. The Chairs of the full House and Senate Appropriations Committees have said their goal is to pass all Fiscal Year 2016 spending bills before the end of Fiscal Year 2015 on September 30. However, if the bills are not passed and signed by the President by then, one or more Continuing Resolutions would likely be enacted. Such measures provide stop-gap funding for those agencies whose regular appropriations have not yet been enacted.

House Budget Resolution

One potential impediment to an NIH funding increase in Fiscal Year 2016 is the Budget Resolution passed by the House on May 5. This is not a bill and it does not go to the President for signature and enactment into law. Rather, it is intended to guide appropriations for the entire government. This blueprint assumes that the Congress would cut spending by more than $5 trillion over the next decade, eliminate the deficit, and create a surplus in 2024. The new Budget Resolution continues the practice of imposing caps on discretionary spending. There is an expectation that the House and Senate appropriations sub-committees will operate within these caps, and each committee is given a target spending ceiling. The President has proposed a legislative change to raise these caps.

Special Statutory Funding Program for Type 1 Diabetes Research

On April 16, 2015, the President signed the *Medicare Access and CHIP Reauthorization Act of 2015.* One provision extended the Special Statutory Funding Program for Type 1 Diabetes Research for two additional years--Fiscal Years 2016 and 2017--at a funding level of $150

million each year. The NIDDK will continue to administer the program on behalf of the HHS Secretary.

The NIDDK recently convened a workshop to discuss ideas and receive input on research opportunities in type 1 diabetes that could be pursued with unobligated funds during the current fiscal year. Now that the program has been extended, the NIDDK can use these ideas to plan new and expanded initiatives for Fiscal Years 2016 and 2017.

Due to the timing of this Program's extension, it will not be subject to a reduction in its Fiscal Year 2016 funding through sequestration. Prospects for sequestration of the program's funds in Fiscal Year 2017 are uncertain at this time.

V. PRECISION MEDICINE FOR ADVANCING HUMAN HEALTH
Dr. Eric Green, Director, National Human Genome Research Institute (NHGRI)

Dr. Rodgers introduced Dr. Eric Green, who has been the Director of the National Human Genome Research Institute (NHGRI) since late 2009. Dr. Green earned his M.D. and Ph.D. degrees from Washington University in 1987. During his residency training in clinical pathology, he launched his career in genomics research. In 1992, he was appointed Assistant Professor of Pathology and Genetics, as well as a co-investigator, in the Human Genome Center at Washington University. In 1994, Dr. Green joined the newly established Intramural Research Program of the National Center for Human Genome Research, later renamed the NHGRI. There, he held a number of positions, including Scientific Director from 2002 to 2009, before succeeding Dr. Francis Collins as Institute Director. While directing an independent research program for almost two decades, Dr. Green has been at the forefront of efforts to map, sequence and understand eukaryotic genomes. His work included significant, start-to-finish involvement in the Human Genome Project. These efforts eventually blossomed into a highly productive program in comparative genomics that has provided important insights about genome structure, function and evolution. Dr. Green has authored and co-authored nearly 350 scientific publications.

Dr. Green focused his remarks on the origin, vision, and planning of a new Presidential Initiative on Precision Medicine. He noted that President Obama is very interested in and supportive of biomedical research--particularly genomics. When he was a Senator, the President introduced a bill entitled the Genomics and Personalized Medicine Act of 2006, and strongly advocated for the idea of advancing medical care using genomic information. Although the bill did not move forward, it was indicative of his views. As President, his interest in genomics is reflected in his selection of two leaders in the field for top posts--Dr. Francis Collins as NIH Director, and Dr. Eric Lander as Co-Chair of the President's Council of Advisors on Science and Technology. Moreover, key White House positons are held by individuals with knowledge of biomedical research generally.

In June 2014, the President asked a small group of experts to meet in the Oval Office to strategize regarding opportunities to launch a bi-partisan initiative that would be part of his

legacy. It became clear that he was interested in including genomics in a broader vision. The President decided on the concept of precision medicine, which encompasses extending knowledge about genomics, lifestyle, environmental exposure, and other areas to improve individualized medical care for the advancement of human health. One factor in the President's decision was reportedly a National Research Council publication that put the phrase "precision medicine" on the map, and provided a conceptual foundation for a major U.S. initiative (*Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease.* National Academies Press, 2011). Dr. Green elaborated on the concept of precision medicine. He said that the physicians and healthcare providers understand that current medical care is based on the expected response of the average patient; however, future medical care will be based more on the uniqueness of individuals. This concept has existed for many years; for example, in the use of prescription eyeglasses precisely tailored to an individual's vision needs.

The President concluded that the time is right to undertake a large, bold initiative to propel this field forward with rigorous, multidisciplinary research. The NIH was assigned the lead role, with the involvement of several other agencies, to develop a planning document that was presented to the President in October 2014 at a meeting that included Francis Collins, Eric Lander, Secretary Burwell, and others. On January 28, the President named and briefly described the Initiative in his State of the Union Address. On January 30, he formally announced and provided details about the Initiative in the East Room of the White House. During a visit to the NIH that same day, Secretary Burwell underscored the President's commitment. Also on January 30, *The New England Journal of Medicine* posted an online article by Drs. Francis Collins and Harold Varmus describing the rationale and general plans for the Initiative.

Since the Initiative's announcement, there have been indications of bi-partisan support in the Congress, which would be essential for funding. The scientific community has responded favorably, and coverage by the lay press has been positive. Moreover, the private sector is showing great interest in partnering with the scientific community. For example, Apple is promoting a "research kit" that provides apps and opportunities for people to participate directly in biomedical research by using their iPhones. The term "precision medicine" is becoming more widely known and used.

Vision for the Precision Medicine Initiative

Dr. Green described the vision for the Initiative. The objective of the Initiative's near-term component is to achieve research successes with regard to cancer, which is a model disease for precision medicine. The objective of the longer-term component is creation of a National Research Cohort of at least one million volunteers to generate a knowledge base for precision medicine. Some policy changes will likely be needed to remove barriers to clinical implementation. Federal rules regarding the protection of research participants will need updating. Also, changes will be needed to advance FDA oversight of precision medicine products. Regarding policy changes, Dr. Green directed the Council's attention to Dr. Eric

Lander's article: "Cutting the Gordian Helix: Regulating Genomic Testing in the Era of Precision Medicine" (*The New England Journal of Medicine*, February 17, 2015).

Dr. Green elaborated on the vision for a blended National Cohort of Volunteers, which would include not only new participants, but also cohorts already funded by the NIH. Genomic data, lifestyle information, and biological samples would be linked to electronic health records. A new model of "doing science" would be developed, with an emphasis on engaging participants; providing for open, responsible data sharing; and ensuring strong privacy protections. The health care system would be not only a system for delivering health care, but also a "learning system."

Dr. Green said that the need for a National Research Cohort has been recognized for many years. For example, in 2004, when Dr. Collins was the Director of the National Human Genome Research Institute, he wrote a commentary entitled: "The Case for a U.S. Prospective Study of Genes and Environment" (*Nature* 429**:**475-477, May 27, 2004). Dr. Collins said: "Information from the Human Genome Project will be vital for defining the genetic and environmental factors that contribute to health and disease. Well-designed case-control studies of people with and without a particular disease are essential for this, but rigorous and unbiased conclusions about the causes of diseases and their population-wide impact will require a representative population to be monitored over time (prospective cohort study). The time is right for the Unites States to consider such a project."

Dr. Collins' 2004 commentary laid out many of the ideas now being pursued, and the years since its publication have produced changes that enable the transformation of those concepts into the Precision Medicine Initiative. For example, knowledge has rapidly accumulated about the workings of the human genome and the role of genomic variances in disease states. Today, over 95 percent of health care providers use electronic health records, which provide a wealth of data for analysis. Technologies for monitoring physiology and lifestyle have advanced enormously--providing a rich source of health-related information. Over 50 percent of Americans now use Smartphones, which could easily be used by a National Research Cohort to capture and transmit information to enrich scientific data about human health and disease. At the same time, the field of data analytics is exploding. Importantly, more people want to participate in biomedical research than in the past--a change that may be related to social media. However, individuals want to participate as partners in research, not just subjects or patients. Citizen-science and crowdsourcing movements reflect these energies. These are some of the factors that have helped moved Dr. Collins' 2004 concept into a 2015 reality.

As the Initiative moves forward, early signs of success would likely emerge. For example, rigorous testing of pharmacogenomics could be undertaken to identify the right drug at the right dose for the right patient. New therapeutic targets could be developed by identifying loss-of-function mutations protective against common diseases. Examples of such new targets already include identification of the *PCSK9* gene for cardiovascular disease and the *SLC30A8* gene for type 2 diabetes. New insights about prevention could be gained from studying the currently

unexplained resistance of some individuals to a disease for which they have a genetic vulnerability. New methods could be developed to advance and evaluate the use of mobile health (mHealth) technologies for the prevention and management of chronic diseases. These are just some possible early successes one can think of for the Initiative.

Planning and Implementation – Next Steps

In February 2015, the NIH convened a meeting to strategize about the directions of the Initiative and to identify issues associated with building the National Research Cohort. Over 1,700 individuals joined the meeting remotely through live videocasts, and the social media coverage was extensive. This type of brainstorming will continue. Upcoming events, including workshops, will be posted on the NIH website (www.nih.gov/precisionmedicine).
There is also a White House website for the Initiative.
https://www.whitehouse.gov/precision-medicine

To help guide the Initiative, Dr. Collins has established a Working Group under the Advisory Committee to the Director, NIH (ACD). The Group is tri-chaired by Richard Lifton, M.D., PhD., Bray Patrick-Lake, M.F.S., and Kathy Hudson, Ph.D. The Working Group is slated to present an interim report to the full Advisory Committee in September 2015, including a plan and strategic vision for developing the National Research Cohort. A Request for Information has already gathered input regarding existing cohorts that could be incorporated into the larger effort. To draw upon broad expertise and input from stakeholders, meetings and workshops are helping to inform this highly transparent planning process. Coordination with other relevant agencies is continuing. Dr. Green noted that detailed plans for the Precision Medicine Initiative will likely evolve over time as new insights are gained, in much the same way as the Human Genome Project developed. It will be important for the scientific community to remain nimble as the Initiative moves forward and details are worked out.

Regarding implementation, the near-term, cancer-focused part of the Initiative will be directed by the National Cancer Institute, which has its own advisory process and will begin by ramping up ongoing efforts. Longer-term efforts will be implemented in a trans-NIH model involving a group of Institute Directors, including the NIDDK Director. The group will be chaired by Dr. Green and the Director of the National Heart, Lung and Blood Institute, Dr. Gibbons.

Contingent on congressional appropriations, the first funding opportunities are slated to be announced in the Fall of 2015. Funding is expected to begin in Fiscal Year 2016, in coordination with other U.S. government agencies. The estimated budget for starting the Initiative is $215 million.

Council Questions and Discussion

Is $215 million sufficient for this Initiative? Dr. Green responded that $215 million is the amount estimated to start the Initiative, with about $130 million of that going toward first steps in creating a National Research Cohort. He said that he did not want to get ahead of the advisory and planning process, but that he would imagine some pilot studies might be undertaken. Answers would likely be sought to fundamental questions about how to build new cohorts and integrate existing ones into the Initiative. Future budget estimates will need to be developed as the Initiative moves forward.

How does this U.S. Initiative compare with similar efforts abroad? Dr. Green said that several other countries have already invested in this type of initiative. The Precision Medicine Initiative is important to the enablement of U.S. science.

What impact will the Initiative have on health disparities? If steps are not taken to ensure that participation in the Initiative is representative of diversity in the U.S., could it unintentionally increase health disparities? Dr. Green responded that there are five groups of NIH staff from multiple Institutes who are looking at major issues, including ways to achieve diversity in the National Research Cohort.

How will the role of the environment in health and disease be included in the Initiative? Dr. Green said that the development and application of technologies will likely be the key to providing new insights about environmental factors. There is a great opportunity for public-private partnerships in this area. It is possible, for example, that the development of biosensors may parallel the process by which achievements have been made in gene sequencing technologies. The NIH will make strategic investments in technologies that will further science and human health.

Is there an effort underway to encourage companies that market systems for electronic medical records to increase the quality of the data, and also obtain information from patient-reported outcomes, including glucose levels? Dr. Green replied that this is an incredibly complicated area that is one of several being addressed by the Office of the National Coordinator for Health Information Technology within the Department of Health and Human Services. The support of the President may further progress in this area. The activism of patients who want input into the management of their own medical data may also contribute to progress.

VI. COUNCIL FORUM: NIDDK Physician-Scientist Workforce Review
Dr. Gregory Germino, NIDDK Deputy Director

Dr. Rodgers began the Forum by commenting on the important, central role that physician-scientists have traditionally had in the biomedical research enterprise. For decades, concerns have been voiced about declining MD participation in biomedical research. In September 2013, NIDDK Deputy Director, Dr. Gregory Germino, presented data associated with the aging of the cohort of MDs holding NIDDK R01 research grants, and the entry of MDs into the NIDDK Research Career Award program--the K Award Program. The purpose of the Council Forum was to provide the Council with an update on these issues, as well as some findings and recommendations of a Physician-Scientist Workforce Working Group of the Advisory Committee to the Director, NIH. Dr. Rodgers encouraged the Council to suggest ways the Institute might enhance physician-scientist representation in the NIDDK portfolio.

Dr. Germino began his presentation by describing the unique and valuable perspective that physician-scientists bring to research. They combine experience in understanding and caring for patients with the analytic skills of basic research. MDs can speak the language of both clinical medicine and basic science, and can thus effectively facilitate the translation and integration of fundamental discoveries into medical practice. Dr. Germino noted that a recent report of the Advisory Committee to the Director, NIH, pointed out that 17 percent of Nobel Laureates in Physiology or Medicine over the last 25 years had an MD degree; as do 69 percent of the current NIH Institute Directors and 70 percent of the Chief Scientific Officers at the top 10 pharmaceutical companies. Clearly, the role of MDs in conducting and leading research endeavors has been and is significant.

Update on Trends

Dr. Germino recounted the long-term trends he presented data to the Council in September 2013. Over time, a decline had occurred in the proportion of NIDDK Principal Investigators with an MD. Fewer MDs had entered the basic science research track. A 35 percent decline had occurred in the participation of MDs in K08 career development awards, which are oriented toward basic research. This decline had been offset only partially by the increase of MDs receiving the clinically oriented K23 research career award. Fewer Early Stage Investigator Awards had been made to MDs. The net result of these trends was that the median age of MD Principal Investigators in the NIDDK portfolio was rising faster than that of MD/Ph.Ds. and Ph.Ds. Median age is extremely important because it indicates whether a cohort of NIDDK investigators is being sustained by the entry of new investigators to replace those who are leaving the research enterprise.

Dr. Germino presented data showing that the trends he identified in 2013 have continued over the past two years. For example, the total number of NIDDK K08 awards to MDs has continued to decline from 2012 to 2014. This decline has not been offset to any great degree by the number of K23 awards to MDs. The percentage of ESIs who are MDs remains relatively low and only modestly outpaces the percentage of ESIs who are MD/Ph.D.s. In addition, the median age of MD recipients of R01 awards has continued to increase, which is a strong indication that the

cohort of MD research investigators within the NIDDK portfolio is not being replenished. Dr. Germino emphasized that the major underlying problem appears to be the drop-off in the number of MDs who apply for K awards, which are an important precursor of R01 grant activity. Dr. Germino emphasized that the issue is the pipeline for K awards, not the competition for R01 grants. MDs compete favorably for NIH funding when they do apply, so there is no systematic bias against them in peer review.

Deeper Analysis of MD and MD/PhD Trends

The continuation of long-term trends suggests that, absent some intervening action, MD representation in the NIDDK workforce may continue to decline further. The Institute continues to collect and analyze data to gain a better understanding of the mechanisms underlying these trends, and where adjustments may be needed in the career development pipeline. To that end, Dr. Germino presented a new analysis of physician-scientists in the NIDDK R01 portfolio based on whether or not their activities are coded by NIH as involving "human subjects research" (a surrogate for clinical research). Activities not so coded can be viewed as oriented toward basic research.

Dr. Germino said that there are two categories of NIDDK investigators whose median age has risen over the past decade: MDs and MD/PhDs whose research does not involve human subjects. In contrast, the median age for other categories of researchers has remained relatively stable, which suggests that those individuals are entering and leaving the NIDDK research enterprise at approximately the same rate. These age-related data suggest a problem with the replacement rate for MDs and MD/PhDs involved in basic research in the NIDDK portfolio. The issue is not only the proportional representation of MDs, but also their absolute numbers. In 2013, across the entire Institute, there were only five MDs involved in basic research who received (new/competing) New Investigator R01 awards.

Using involvement in non-human subjects research as a surrogate for basic research, Dr. Germino presented the following points regarding the long-term representation of MDs in NIDDK R01 grant activity:

- The median age of MDs submitting unsolicited R01 grant applications oriented toward basic research is rising faster than for other groups.

- The median age of MDs receiving unsolicited R01 awards oriented toward basic research is rising faster than for other groups.

- The number of MDs receiving one or more unsolicited R01 awards oriented toward basic research in a fiscal year has trended down since fiscal year 2004. In contrast, the number of MDs receiving one or more unsolicited R01 award(s) involving more clinically oriented research (human subjects research) has trended up.

- The average age of MDs receiving an R01 award oriented toward basic research has trended

up much faster and consistently than the average age of MDs receiving an R01 award involving clinically oriented research (i.e., human subjects research).

Collectively, these data suggest that there may be a problem associated with entry into the NIDDK R01 biomedical research workforce of early career-stage MDs focused on basic research. Further analysis has shown that these trends in R01 grants appear linked to the annual number of new NIDDK Research Career Development awards--K awards--going to MDs from 2004-2014. The overall number of K applications from MDs has decreased by about 40 percent, and the overall number of competing K awards to MDs has also declined by about 40 percent. Applications from and awards to MDs are down for basic-research focused K08s and up for clinically focused K23s. Thus, fewer MDs are applying for K awards, and those who actually do apply tend to focus on clinically oriented research. These trends in K08 and K23 applications from and awards to MDs are also reflected in the training background of NIDDK new Principal Investigators. Moreover, they are evident in a shift in research focus--from a basic to a more clinical focus--among MDs who receive their first R01 award.

Working Group of Advisory Committee to the Director, NIH (ACD)

Dr. Germino said that the NIDDK trends align with some of the findings of the Physician-Scientist Workforce (PSW) Working Group, which was established under the Advisory Committee to the Director, NIH (ACD). He emphasized, however, that the Working Group defined physician-scientists very broadly to include nurse-scientists, veterinarian-scientists, and dental-scientists. In the NIDDK portfolio, physician scientists are mostly MDs and MD-PhDs. Furthermore, the charge to the Working Group was very broad. The Group was asked to develop approaches that can inform decisions about the development of the U.S. physician- scientist workforce; analyze the size and composition of the workforce and consider the impact of NIH funding policies; assess needs and career opportunities for physician-scientist trainees; and identify incentives and barriers to entering the physician-scientist workforce.

Dr. Germino noted that the Working Group presented a report on its findings and recommendations to the full ACD in June 2014 (http://acd.od.nih.gov/reports/PSW_Report_ACD_06042014.pdf).
Some of the major findings included the following. The physician-scientist pool is stagnating. The total number of physician-scientists engaged in research has been unchanged over the past decade. The physician-scientist pool is aging in a similar but more pronounced way than the biomedical workforce pool. Major challenges for physician-scientists are the availability of research funding, average educational debt, increased length and complexity of training, striking a work-life balance, competing clinical vs. research responsibilities, and requirements regarding credentialing, work hours, and other activities.

Dr. Germino highlighted the following nine Working Group recommendations, and commented on related NIDDK efforts and goals.

1. ***Sustain strong support for MD/PhD programs.*** Dr. Germino said that in contrast to NIH

wide data that show that ~50% of the Physician-Scientist workforce are MD/PhDs, only 31% of the physician-scientists involved in NIDDK research are MD/PhDs. This has important implications since the focus by the ACD committee on MD/PhDs may not address NIDDK's workforce problem. When queried, MD/PhDs have said that their career choices were made as early as middle school or high school, often based on models provided by family members and educators. While individuals who enter MD/PhD training programs have a strong interest in and commitment to science, they are unlikely to engage with NIDDK investigators and programs until they have completed that training. Therefore, to sustain or increase the representation of MD/PhDs in the NIDDK portfolio would probably require the Institute to reach out to these individuals early in their scientific careers, or to link into their MD/PhD training period. The NIDDK also will have to direct more effort on training and retaining MD physician-scientists given the high proportion they make of the NIDDK workforce.

2. ***Shift National Research Service Award (NRSA) postdoctoral training awards to support proportionally more individual fellowships (F Awards) vs. institutional training grants (T Awards).*** The NIDDK had shifted the focus of its NRSA programs toward fellowships prior to the Working Group's recommendation. The Fellowship Program is viewed as being the more successful of the two awards in terms of outcomes. Its success may relate to the relatively young age and prior research exposure of the Fellows. Dr. Germino emphasized, however, that Institutional Training Grants are still an important research training mechanism for individuals who are not exposed to science until quite late in their careers.

3. ***Continue to address the gap in R01 grant award rates between new and established investigators.*** The NIDDK has established an automatic five percent higher payline advantage for early stage investigators. NIDDK Program Staff also identify for possible support those meritorious applicants who have just missed the payline.

4. ***Develop more effective tools for assessing the strength of the biomedical workforce and tracking career progress.*** The NIDDK is enhancing its own analytic capabilities, and taking advantage of those available through central NIH. The NIDDK's data analyses have revealed a pipeline problem in the Institute's K08 Program for MDs, especially in basic research. The NIDDK has shown that its K08 recipients fare as well as any other comparable K group (e.g., K01 or K23 awardees) in obtaining R01 grant awards--if they apply.

5. ***Establish physician-scientist specific K99/R00-equivalent granting mechanism.*** The NIDDK has the largest K award program for physician-scientists at the NIH. Moreover, MD recipients of the Institute's K awards have high rates of applying for and receiving regular research grants. Discussions are under way in the Institute as to whether a new K99/R01 award is needed to recruit and retain physician-scientists in the NIDDK portfolio, or whether other mechanisms should be explored.

6. ***Expand loan repayment programs and increase dollar amounts of loan forgiveness.*** The NIDDK recognizes that difficulties exist in expanding the funding levels for these programs. However, there may be opportunities to restructure the programs to increase loan limits for investigators and make eligibility more flexible to include groups like MDs that work in basic science.

7. ***Support pilot grant programs to test existing and novel approaches to improve and/or shorten research training.*** Opportunities may exist for pilot programs to shorten the research training period, especially for MDs and MD-PhDs. It may be possible to shorten clinical research training for individuals who have already developed and maintained clinical and/or research capabilities. Dr. Germino said that some academic institutions have already established successful models.

8. ***Intensify efforts to increase diversity in the physician-scientist workforce.*** The NIDDK seeks to promote diversity in the physician-scientist workforce, and other areas of its portfolio. Institutional research training grants are one of several avenues the NIDDK uses for increasing diversity of the workforce.

9. ***Leverage the existing resources of the CTSA Program to obtain maximum benefit for training and career development.*** A major NIDDK goal is to leverage existing investments in all its programs.

Dr. Germino elaborated further on the success of the investigators who complete the Institute's K award program. Over three-quarters of K awardees apply for R01 grants, and have high success rates. Moreover, an NIDDK analysis of cohorts of awardees has shown that a very high percentages of K awardees have remained in research careers over relatively long periods of time. Likely factors that contribute to the K Program's success in transitioning investigators to long-term research careers include the shepherding of awardees by NIDDK Program Directors; NIDDK conferences for K awardees regarding the workings of the NIH; and an R03 small grant program that enables awardees to receive a modest additional amount of funds to develop their research activities during their K award period. On the other hand, it is troublesome that almost a quarter of the K awardees never apply for an R01 grant and the attrition rate for those who apply and fail to get an award after one failed submission is relatively high. Dr. Germino emphasized that the NIDDK invests substantial resources in its K Program, and would like to reduce this drop-out rate of highly skilled research investigators.

The NIDDK recognizes that some of the reasons that K awardees may drop out of research include: inability to redirect a faulty hypothesis, slow start-up period, fear of failure, misperception of career risk, and change in personal circumstances. Possible corrective actions to reduce drop-outs might be to provide for improved mentoring and a better safety net of bridge funding so that an investigator has time to gather more data or redirect an idea. It may be helpful to have a better strategy to communicate to K awardees their excellent likelihood of a productive research career based on the success rates of their peers in obtaining NIH regular research grants. Regarding a safety net, Dr. Germino noted that the NINDS has established a K02 program that

provides up to three years of support to investigators who complete a K08 or K23 award. The only requirement is that they must apply for an R01 grant by the third year of support. Data on the NINDS K02 recipients show a significant improvement in R01 application numbers and success rates.

Dr. Germino closed his presentation by suggesting some ideas for discussion. He asked the Council to suggest ways the NIDDK could enhance the size of the pipeline for and retention rate in science of MDs--especially MDs doing basic research. Three ideas consistent with recommendations of the Working Group of the Advisory Committee to the NIH Director are: (a) continue to focus on Fellowship training awards; (b) continue/enhance investment in the Loan Repayment Program; and (c) continue support of New Investigators. Other ideas are to highlight diversity of the workforce and a commitment to basic research in NIDDK core values. The NIDDK could also consider Special Emphasis awards for MDs engaged in basic research; creation of a new K award for MDs, similar to the K02 used by the NINDS; or creation of a K99/00 award for MDs. Dr. Germino asked Council members to consider these ideas and suggest others. He asked for feedback on the Working Group's recommendations so that the NIDDK can convey ideas to the NIH level before implementation decisions are made.

Council Questions and Discussion

Council members generally agreed that the data regarding the representation of MDs and MD-PhDs in NIDDK basic research is sobering. The data underscore the importance of early exposure to research. Lifestyle, debt, lack of mentoring, inadequate monetary support and other factors are all disincentives that may influence the decision of MDs to pursue a career as a physician-scientist.

Regarding institutional support, it was noted that institutions and subspecialty professional organizations could help increase funding, especially salary levels for early stage investigators. It might be helpful for the NIDDK to develop a pilot with a few institutions. One Council member noted that some institutions are simply unable to provide the support required by NIH for K99 awards, and they struggle with the programmatic expectation that the awardee change institutions when transitioning from the K99 to R00 phase of the award. This could hinder rather than help career development if investigators lose the networks they have established, particularly MDs who are often well-networked within their training home. It was noted that the commitment of academic research institutions goes beyond financial support of investigators.

Regarding the possible creation of a K99/R00 award for physician-scientists, Dr. Germino said that such an award would likely involve some co-investment by institutions. Perhaps as an alternative, the NIH and the institution would accept some shared risk in supporting a highly promising K awardee who just missed getting an R01. The program would provide a bridge award like the K02 to give candidates time to refine their concepts for independent research before submitting an R01 grant application. The K02 award is an interesting concept that appears to be working well for NINDS, and it could be modified by the NIDDK to incorporate institutional commitment.

Other approaches were discussed, including making the R03 award more robust. The R03 might be restructured to include a requirement for submitting an R01 application that could be funded at a lower level and for a shorter period of time than a traditional R01 grant. The institution could play a role in selecting promising candidates. Additionally, there may be new ways of incentivizing physician-scientists to work in teams early in their careers in order to promote a nurturing environment and a commitment to science.

VII. SCIENTIFIC PRESENTATION:

Origin and Fate of Myofibroblasts in Liver Fibrosis

David Allen Brenner, M.D., Vice Chancellor for Health Sciences and Dean of the School of Medicine, University of California, San Diego (UCSD)

A leader in gastroenterological research, and a widely recognized clinician and teacher, Dr. Brenner specializes in liver diseases. He is widely respected as a translational scientist whose work bridges the laboratory and clinical settings. He has focused on understanding the molecular pathogenesis of fibrotic liver disease and the genetic basis of liver disorders as the foundation for improving prevention and treatment of liver disease. Dr. Brenner served for five years as Editor-in-Chief of the journal Gastroenterology, and currently serves on a number of editorial boards. Dr. Brenner earned his M.D. from the Yale University School of Medicine. After completing his residency at Yale-New Haven Medical Center, he served as a research associate in the Genetics and Biochemistry Branch at NIH. Dr. Brenner first went to UC San Diego in 1985 as a gastroenterology fellow. He later joined the medical school faculty, and served as a physician at the Veterans Affairs San Diego Healthcare System. In 1993 he became Chief of the Division of Digestive Diseases and Nutrition, University of North Carolina at Chapel Hill. Then, from 2003 to 2007 he served at the Columbia University Medical Center College of Physicians and Surgeons, as Samuel Bard Professor and Chair of the Department of Medicine, a Member of the Herbert Irving Comprehensive Cancer Center, a Member of the Columbia University Institute of Nutrition, and Physician-in-Chief of New York Presbyterian Hospital/Columbia. He returned to UCSD in 2007.

VIII. CONSIDERATION OF APPLICATIONS

A total of 1884 grant applications (704 primary and 1180 dual), requesting support of $510,391,181 were reviewed for consideration at the May 13, 2015 meeting. An additional 1030 Common Fund applications requesting $1,383,850,634 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1218 applications requesting $ 362,632,400 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the May 13, 2015 meeting.

IX. ADJOURNMENT
Dr. Rodgers

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the Council members, presenters, and other participants. He thanked the Council members for their valuable input. There being no other business, the 198th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on May 13, 2015.

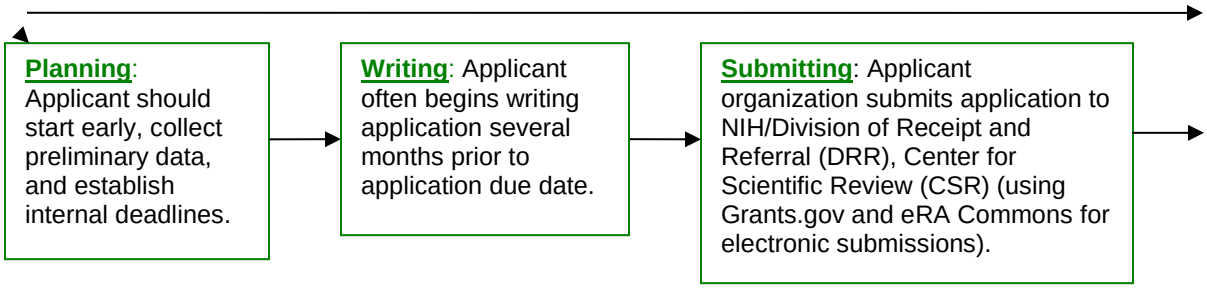
I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council

Grants Process At-A-Glance

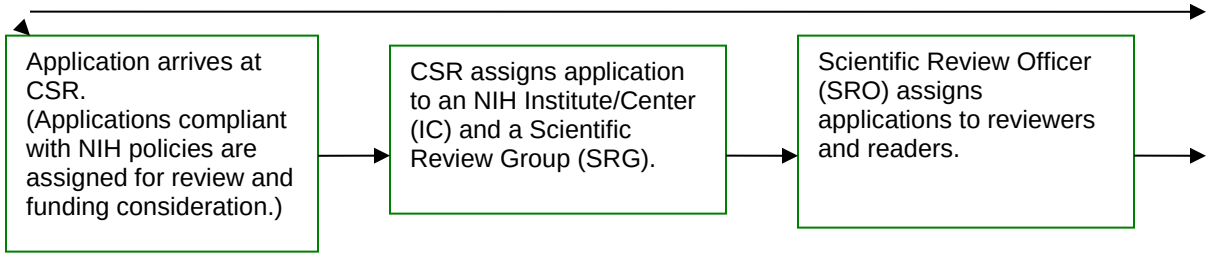
The following NIH "Grants Process At-A-Glance" chart is provided as a sample of the general time element necessary for a competing application to proceed from Receipt and Referral through the Peer Review process to negotiation and award.

Planning, Writing, Submitting



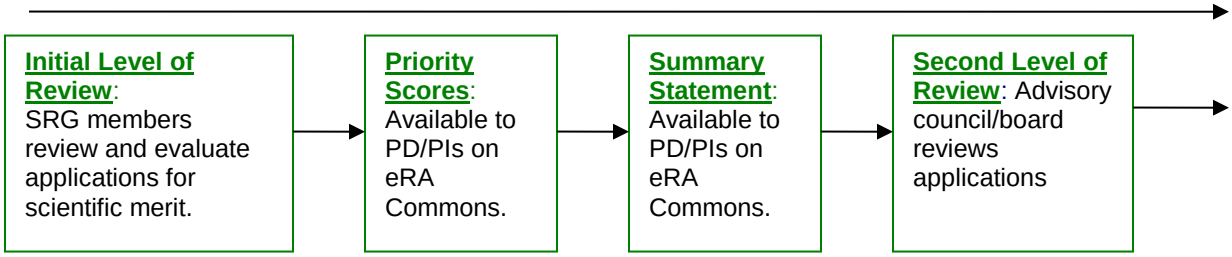
Receipt and Referral

Months 1 to 3



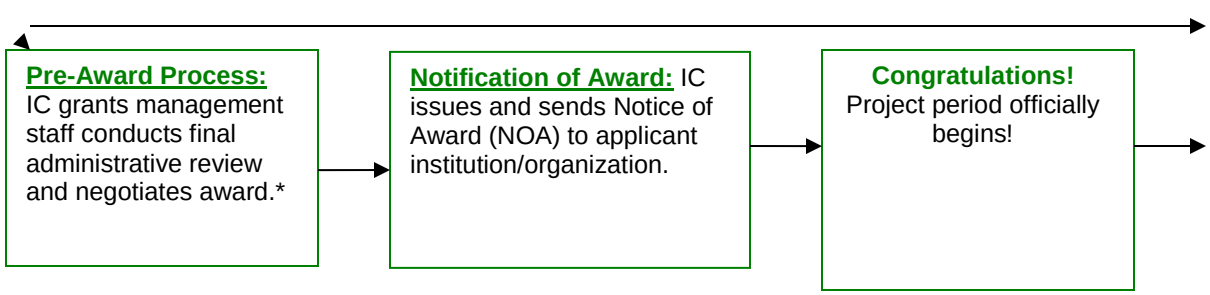
Peer Review

Months 4 to 8



Award (*Requests additional information needed just-in-time for award.)

Months 9 to 10

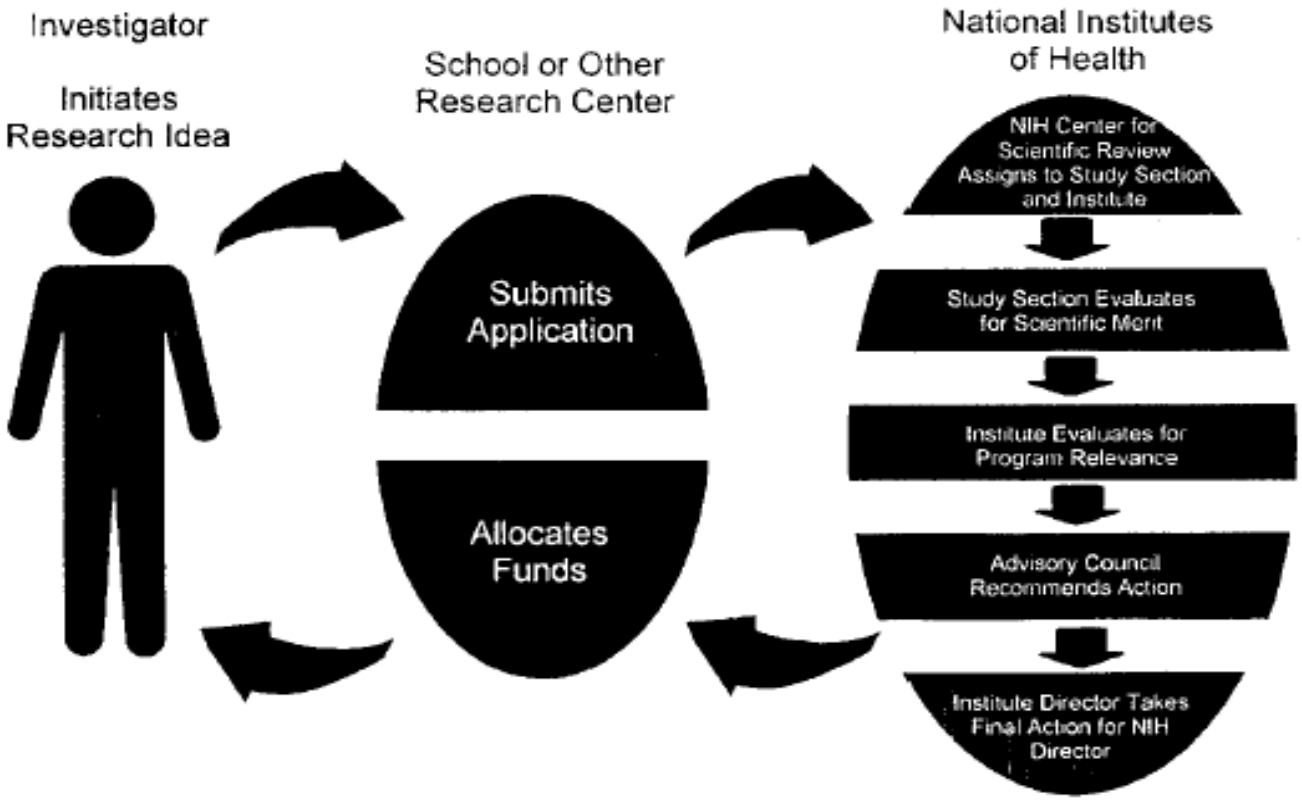


Post-Award Management

Administrative and fiscal monitoring, reporting, and compliance.

Note: Timeline is based on the standard grants process. It does not reflect a shorter timeframe for grants undergoing expedited review.

Review Process From Application to Award



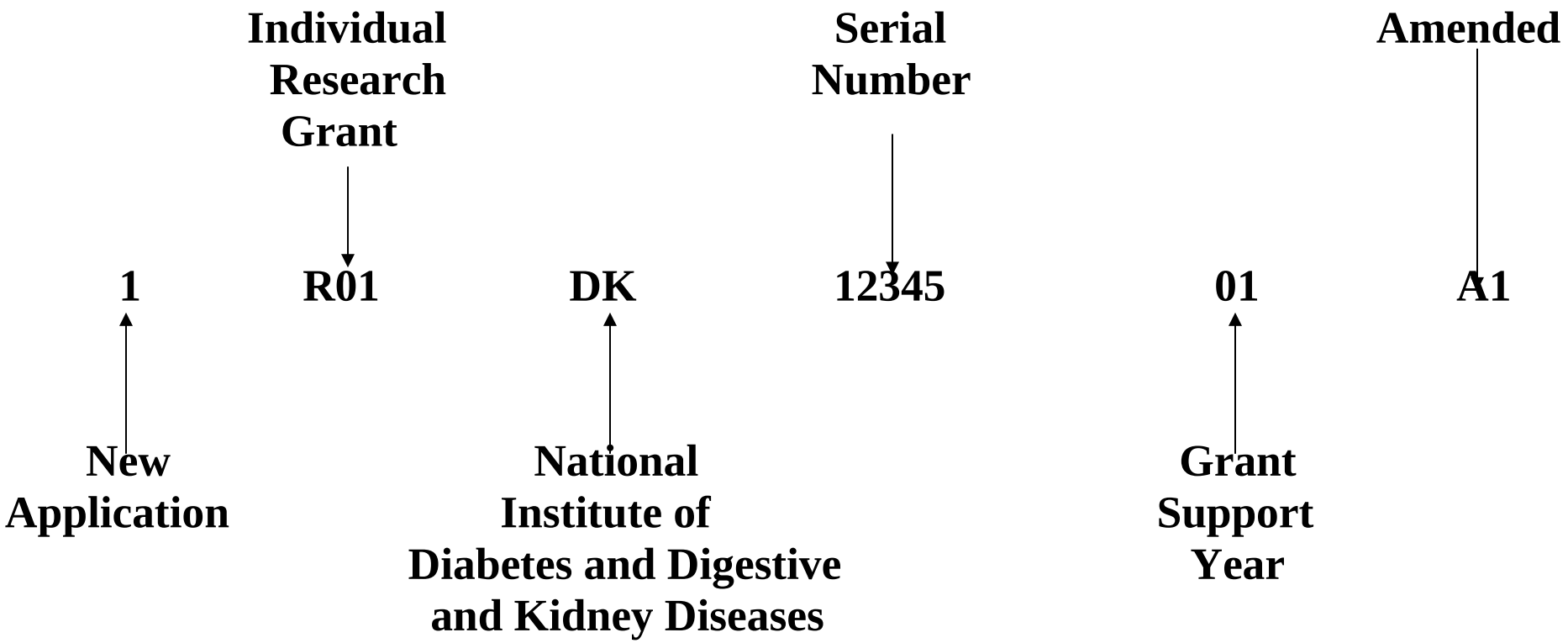
NIH Grant Receipt, Review, and Award Schedule

Jan-May **May-Sept** **Sept-Jan**	**Receipt Dates**
June-July **Oct-Nov** **Feb-Mar**	**Review Dates**
Sept-Oct **Jan-Feb** **May-June**	**National Advisory Council/Board Dates**
Dec1 **Apr 1** **July 1**	**Earliest Possible Beginning Date**

NIH Funding Instruments

Grant (NIH as Patron)	Cooperative Agreement (NIH as Partner)	Contract (NIH as Purchaser)
Project Conceived by Investigator	Project Conceived by Investigator or NIH	Project Conceived by NIH
NIH Supports or Assists	NIH Supports or Assists	NIH Acquires Services or Product
Performer Discusses Details and Retains Scientific Control	NIH Participates in Direction	NIH Exercises Direction and Control
NIH Maintains Cognizance	NIH Monitors	NIH Closely Monitors
Accomplishes a Public Purpose	Accomplishes a Public Purpose	For the Direct Benefit of the Government

Sample Application Number

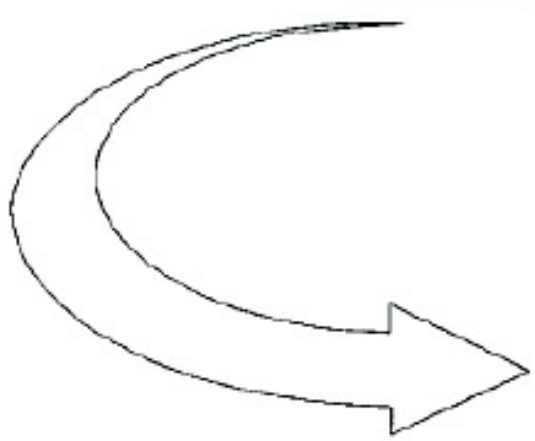


Dual Review System for Grant Applications

First Level of Review

Scientific Review Group (SRG)

- Provides Initial Scientific Merit Review of Grant Applications
- Rates Applications and Makes Recommendations for Appropriate Level of Support and Duration of Award



Second Level of Review

Council

- Assesses quality of SRG Review of Grant Applications (*See Advisory Council Voting Options)*
- Makes Recommendations to Institute Staff on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy

Second Level of Review: Advisory Council Voting Options

- Concurrence with study section action
- Modification of study section action
- Deferral for re-review

NIDDK Makes Funding Decisions Based on:

- Scientific merit
- Program considerations
- Availability of funds

Initial Review Process

Overview

NIH policy is intended to ensure that grant applications submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects."

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils are composed of both scientific and lay members chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council may be recommended for funding.

First Level of Review

Initial peer review meetings are administered by either the Center for Scientific Review (CSR) or another NIH IC. The focus of review is specified in the Funding Opportunity Announcement. Peer review meetings are announced in the Federal Register. The meetings are closed to the public, although some meetings may have an open session; the Federal Register provides the details of each meeting.

A. Peer Review Roles and Meeting Overview

Scientific Review Officer:

Each SRG is led by a Scientific Review Officer (SRO), formerly Scientific Review Administrator (SRA)]. The SRO is an extramural staff scientist and the Designated Federal Official responsible for ensuring that each application receives an objective and fair initial peer review, and that all applicable laws, regulations, and policies are followed.

SROs:

- Analyze the content of each application, and check for completeness.
- Document and manage conflicts of interest. See NOT-OD-11-120 issued on September 26, 2011, and briefly described at end of this chapter.
- Recruit qualified reviewers based on scientific and technical qualifications and other considerations, including:
    - Authority in their scientific field (42 CFR 52h.4)
    - Dedication to high quality, fair, and objective reviews
    - Ability to work collegially in a group setting
    - Experience in research grant review
    - Balanced representation
- Assign applications to reviewers for critique preparation and assignment of individual criterion scores.
- Attend and oversee administrative and regulatory aspects of peer review meetings.
- Prepare summary statements for all applications reviewed.

SRG Members

Chair:

- Serves as moderator of the discussion of scientific and technical merit of the applications under review.
- Is also a peer reviewer for the meeting.

Reviewers:

- Declare Conflicts of Interest (COI) with specific applications following NIH guidance. (See COI section below.)
- Receive access to the grant applications approximately six weeks prior to the peer review meeting.
- Prepare a written critique (using Review Critique Fill-able Templates) for each application assigned per the SRO, based on review criteria and judgment of merit.
- Assign a numerical score to each review criterion
- Make recommendations concerning the scientific and technical merit of applications under review, in the form of final written comments and numerical scores.
- Make recommendations concerning protections for human subjects; inclusion of women, minorities, and children in clinical research; welfare of vertebrate animals; and other areas as applicable for the application (see guidance for reviewers on Human Subjects Protection and Inclusion, Human Embryonic Stem Cells, and Vertebrate Animals).
- Make recommendations concerning appropriateness of budget requests (see Budget Information for Reviewers).

Other NIH Staff:

- Federal officials who have need-to-know or pertinent related responsibilities are permitted to attend closed review meetings.
- NIH IC or other federal staff members wishing to attend an SRG meeting must have advance approval from the responsible SRO. These individuals may provide programmatic or grants management input at the SRO's discretion.

Peer Review Meeting Procedures

- Applications are reviewed based on established review criteria (see below).
- Assigned reviewers summarize their prepared critiques for the group.
- An open discussion follows.
- Final scoring of overall impact/priority scores is conducted by private ballot.

B. Peer Review Criteria and Considerations

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Review Criteria for Research Grants and Cooperative Agreements

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria. Reviewers will consider each of the review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects
Inclusion of Women, Minorities, and Children
Vertebrate Animals
Biohazards
Resubmission
Renewal
Revision

Additional Review Considerations. As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations
Select Agent
Resource Sharing Plans
Budget and Period Support

C. Scoring

The scoring system described below was implemented for applications submitted for funding consideration for FY2010 and thereafter (NOT-OD-09-024)

Before the SRG meeting, each reviewer and discussant assigned to an application will give a separate score for each of five review criteria (i.e., Significance, Investigator(s), Innovation, Approach, and Environment for research grants and cooperative agreements; see above). For all applications, even those not discussed by the full committee, the individual scores of the assigned reviewers and discussant(s) for these criteria are reported to the applicant.

In addition, each reviewer and discussant assigned to an application gives a preliminary overall impact/priority score for that application. The preliminary scores are used to determine which applications will be discussed in full. For each application that is discussed at the meeting, a final impact/priority score is given by each eligible committee member (without conflicts of interest) including the assigned reviewers. Each member's score reflects his/her evaluation of the overall impact that the project is likely to have on the research field(s) involved, rather than being a calculation of the reviewer's scores for each criterion.

The scoring system utilizes a 9-point rating scale (1 = exceptional; 9 = poor). The final overall impact/priority score for each discussed application is determined by calculating the mean score from all the eligible members' impact/priority scores, and multiplying the average by 10; the final overall impact/priority score is reported on the summary statement. Thus, the final overall impact/priority scores range from 10 (high impact) through 90 (low impact). Numerical impact/priority scores are not reported for applications that are not discussed (ND), which may be reported as *.* on the face page of the summary statement and typically rank in the bottom half of the applications.

Applicants should contact the Program Officer for the application to seek additional feedback on the score and summary statement.

An application may be designated Not Recommended for Further Consideration (NRFC) by the Scientific Review Group if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

The following guidance has been given to reviewers to determine individual review criterion and overall impact/priority scores:

High Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
Medium Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
Low Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact

D. Summary Statement

Applications that are not discussed at the meeting will be given the designation “ND” as an overall impact/priority score, but the applicant, as well as NIH staff, will see the scores from the assigned reviewers and discussants for each of the review criteria as additional feedback on their summary statement.

Understanding the Percentile

- A percentile is the approximate percentage of applications that received a better overall impact/priority score from the study section during the past year.
- All percentiles are reported as whole numbers
- Only a subset of all applications receive percentiles. Which types of applications are percentiled varies across different NIH Institutes and Centers.
- The summary statement will identify the base that was used to determine the percentile.

E. Appeals

To preserve and underscore the fairness of the NIH peer review process, NIH established a peer review appeal system (see NIH Guide Notice NOT-OD-11-064) to provide investigators and applicant organizations the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was flawed as outlined below. The appeals policy applies to appeal letters received with respect to the initial peer review of all competing applications submitted to the NIH for support for the January 25, 2011 due date and thereafter, including: 1) reviews conducted by the NIH Center for Scientific Review (CSR) and reviews conducted by the NIH Institutes and other NIH Centers; and 2) applications such as fellowship application that typically do not require Council review. This policy does not apply to appeals of the technical evaluation of R&D contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT award.

An appeal is a written communication from a Project Director/Principal Investigator (PD/PI) and/or official of the applicant institution [not necessarily the Authorized Organization Representative (AOR)] that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence of the AOR. An appeal letter will be accepted only if the letter 1) describes a flaw(s) or perceived flaw(s) in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers
- Conflict of interest, as specified in regulation at 42 CFR 52h "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more non-federal peer reviewers
- Lack of appropriate expertise within the SRG
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

The IC cannot deny the PD/PI and/or the applicant institution the opportunity to have an appeal letter made available to Council, but the IC may determine which appeal letters warrant discussion by the Council members, and Council members may raise certain ones for discussion if they so choose. The Council may concur:

- with the appeal, and recommend that the application be re-reviewed.
- with the SRG's recommendation and deny the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

Information from http://grants.nih.gov/grants/peer_review_process.htm.

F. Revised Conflict of Interest Policy for Initial Review

The NIH initial peer review process involves the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of grant and cooperative agreement applications to the National Institutes of Health (NIH). The process, defined in regulation at 42 CFR Part 52h, is extended by policy to other types of applications submitted to the agency.

On September 26, 2011, the NIH issued a revised policy on managing conflict of interest (COI) in the initial peer review of NIH grant and cooperative agreement applications: see NOT-OD-11-120. This announcement provides revised policy for managing COI, the appearance of COI, prejudice, bias, or predisposition in the NIH initial peer review process.

The announcement addresses multi-disciplinary and collaborative research and clarifies the role of non-Federal and Federal employees serving as reviewers. Unlike members of NIH Advisory Councils or Boards, reviewers in the initial level of NIH peer review are not appointed as Special Government Employees and do not submit financial disclosure forms. Therefore, SROs are not in a position to collect financial information from reviewers, but can ask about professional relationships and roles as defined in the revised NIH policy and make determinations about potential bias in the initial peer review process.

The overall goal of the revised policy is to increase transparency and to inform the scientific community. With the dramatic increase in internet capability, reviewers may be looking up financial information about investigators on the websites of the investigators' institutions. Although this COI information is available publicly, SROs should instruct reviewers not to consider COI information about applicants in their reviews, discussions, or evaluations.

Similarly, applicants may be looking up financial information about reviewers on their institutions' websites and submitting appeals of initial peer review on the basis of that information. Therefore, it is important that SROs clearly explain the conflict rules for initial peer review to their reviewers.

Modified Application Submission, Referral and Review for Appointed NIH Advisory Group Members

To recognize their outstanding commitment to service to the NIH, regular members of NIH Boards of Scientific Counselors, NIH Advisory Boards or Councils, and the NIH Peer Review Advisory Committee are extended the option of modified application submission, referral and CSR review.

This alternate process is limited to R01, R21, and R34 applications that would normally be received on standard submission dates (but not special receipt dates) and will be reviewed at CSR. Depending on the timing of the submission and the number of other similar applications received during the pre-meeting time window, NIH staff will decide if the application will be reviewed in a standing Study Section or in a Special Emphasis Panel (SEP). These applications will be processed and assigned to NIH Institute Review Offices or CSR Integrated Review Groups (IRGs) using the standard referral guidelines (http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription/).

This continuous submission process will enable appointed members of chartered NIH advisory groups to submit their applications as soon as they are fully developed. The applications will be reviewed no later than 120 days after receipt. Because of the need to assign an Advisory Council date, the following schedule will be followed. However, applications may be moved to earlier councils following review as timing permits

Schedule for Assignment to Advisory Council Rounds

Council Round	Non-AIDS applications	AIDS applications
May	August 17 - December 16	October 8 - February 7
October	December 17 - April 16	February 8 - June 7
January	April 17 - August 16	June 8 - October 7

Further information and Inquiries

For more information see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-114.html .

A series of Frequently Asked Questions has been prepared (see http://cms.csr.nih.gov/ResourcesforApplicants/ContinuousSubmissionFAQ.htm).

Inquiries may also be addressed to:
Division of Receipt and Referral
Center for Scientific Review
6701 Rockledge Drive MSC 7720
Bethesda, MD 20892-7720
Voice: (301) 435-0715
Fax: (301) 480-1987

Second-Level Review Procedures

The Advisory Council/Board of the potential awarding Institute or Center (IC) performs the second level of review. Advisory Councils/Boards are composed of scientists from the extramural research community and public representatives (NIH Federal Advisory Committee Information). Members are chosen by the respective IC and are approved by the Department of Health and Human Services. For certain committees, members are appointed by the President of the United States.

On June 18, 2010, President Obama issued "Lobbyists on Agency Boards and Commissions," a memorandum directing agencies and departments in the Executive Branch not to appoint or re-appoint federally registered lobbyists to advisory committees and other boards and commissions. On October 5, 2011, the Office of Management and Budget (OMB) issued final guidance to Executive Departments and agencies concerning the appointment of federally registered lobbyists to boards and commissions. This guidance applies not only to advisory committees subject to FACA, but to all other groups as well-even to members of working groups not appointed as SGEs. See *Federal Register* / Vol. 76, No. 193 / Wednesday, October 5, 2011/Notices under OFFICE OF MANAGEMENT AND BUDGET, Final Guidance on Appointment of Lobbyists to Federal Boards and Commissions, AGENCY: Office of Management and Budget. ACTION: Notice of Final Guidance.

Second-level review is the assessment of the quality of the initial review of grant applications. By law, NIDDK's Advisory Council must recommend an application before the Institute can fund it. Second-level review is **not a second scientific review**. Rather, the Council looks at applications with potential barriers to funding such as human subjects and animal concerns or special circumstances such as foreign applications and renewal applications requesting more money than the limit.

The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote. When Council recommends an application for funding, that doesn't necessarily mean it will receive an award. NIDDK makes the final decision.

Applications Requiring Council Discussion

- Applications from Foreign Institutions

  In reviewing and making recommendations on foreign grant applications, the Council members should be aware that ALL of the following criteria must be met in order to be supported by the NIH:

  a. The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing United States resources.
  b. The project has specific relevance to the mission and objectives of NIDDK and has the potential for significantly advancing the health sciences in the United States.
  c. The application must be approved for funding by the Council.
  d. The application may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, and gender and minority requirements.

- Applications With Concerns about Human or Animal Subjects and/or Gender and Minority Representation

The Council will be asked to comment on any application(s) recommended for possible funding with unresolved concerns regarding the involvement of human subjects, the use of animals, and/or gender and minority representation. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern(s).

- Applications That May Not Provide for Appropriate Biosafety, Biocontainment, and Security of Select Agents

  The Council will be asked to comment on any applications recommended for possible funding with unresolved concerns regarding biosafety, biocontainment, and security of select agents. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern.

- Letters of Appeal

  The Council reviews appeal letters that were submitted by investigators subsequent to the peer review of their application and were not resolved by program and review staff. It is the responsibility of NIDDK staff to determine whether a letter is an appeal.

  An investigator may have concerns about and may wish to appeal a procedural aspect of the peer review process. Only letters concerning procedural aspects of a review are considered an appeal. Procedural issues fall under four categories and the applicant must claim one or more of the following:

  a. The initial review was biased.
  b. A conflict of interest existed.
  c. The review group lacked appropriate scientific expertise.
  d. Factual errors entered into the review.

  Differences in scientific opinion that often occur between investigators and reviewers may not be contested through these procedures. In addition, communications from investigators consisting of additional information that was not available to the reviewers are not considered to be appeals.

  The Council has two options when reviewing an appeal letter:

  a. To concur with the outcome of the initial peer review as reflected in the summary statement.
  b. To concur with the claims discussed in the applicant's appeal letter and recommend deferral for re-review either by the same or a different review group.

  Other letters, termed Council communications, are also made available to the Council at the discretion of NIDDK staff.

Special Council Review of Research Applications from Program Directors/Principal Investigators (PDsPIs) with more than $1.0 Million Direct Costs in NIH Support

In an effort to continue responsible stewardship of public funds and to support meritorious and innovative research, NIH has instituted a policy of Special Council Review (SCR) of applications from well-funded investigators: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html. Pending grants going to Council from PDs/PIs who have more than $1 million in direct costs from active NIH Research Project Grants (RPGs) grants will be subjected to additional consideration. It is important to recognize that this is a threshold only; investigators who have more research support

may still receive additional awards as warranted. When making funding recommendations, staff will take into account factors such as: how innovative and distinct the pending project is from the PD/PI's other grants; the type of research (since costs requirements differ substantially by field); the public health priority of the research; and how the absence of an award impacts other collaborative or translational research efforts.

The following SCR policy guidance is designed to achieve these goals.

- Criteria Considered by NIDDK Staff for Determining Applications Subject to SCR

    a. P01s and other Multi-Component RPGs: Only funds acquired[1] through RPGs[2] should be included when calculating a given PD/PI's support.
    b. Only competing RPGs (New and Renewals) to be considered for award to investigators with $1.0M or more of direct cost NIH support are subject to SCR via this policy.
    c. P01s and other Multi-Component RPGs:
        i. Competing Multi-Component RPGs are not subject to SCR unless all of the component leaders have $1.0M or more of NIH support. The rationale for this is that failure to support one or more of the leaders who exceed the limit could significantly detract from the project as a whole.
        ii. Funded P01s and any other multi-component RPGs, including consortium/sub-award costs, contribute to the $1.0M threshold of the Program Director and sub-project leaders. Each sub-project leader's total should include the funds provided directly to him/her only through the P01; core costs should not be included.

- Multiple PD/PI Projects:
    a. Competing Multi-PI applications are only subject to SCR if all the PD/PIs exceed the $1.0M threshold.
    b. In calculating the research support available to a PD/PI who participates in a multi-PI award, the direct cost award amount to the institution should be divided evenly among PIs at that institution. Budgets of multi-PIs at other institutions may be determined using the funds allocated to their subcontract costs.

- Requests for Applications (RFAs):
    a. Pending applications submitted in response to RFAs will not be subjected to SCR. The rationale is that these applications have been solicited by the IC to accomplish a specific purpose. The intent is to award the best proposal(s) designed to achieve the IC's specified goal(s).
    b. Funds provided through these grants will contribute to the $1.0M threshold for the investigators' future applications.

- Competing revisions and administrative supplements:
    a. These types of grants are not expected to be a significant contributing factor in reaching the threshold, since many will not incur future year commitments. However, multi-year supplements are included in grant's out-year commitments and do contribute to the $1.0M threshold. In order to prevent Re-entry and Diversity Supplements from being an impediment

[1] Funds acquired include active RPG awards for the PD/PI (exclusive of projects in no cost extension) when the application subjected to SCR is pending Council review and funds for multi-year projects allocable to the current Fiscal Year (Multi-Yr: R15, DP2, DP3, DP4, RC3, RC4, R55, RC1)

[2] Defined as R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, RC2, RC3, RC4, RL1, RL2, RL5, RL9, P01, P42, PN1, UA5, UC1, UC2, UC4, UC7, UH2, UH3, UH5, UM1, U01, U19, U34, DP1, DP2, DP3, DP4, and DP5.

to an investigator, to the extent possible, these supplements should be excluded from the threshold count.

- Guidelines for Council Consideration (Council role):
  a. When applied to new projects, SCR will focus on the unique opportunities afforded to the investigator to advance his/her research in directions that are highly promising and distinct from his/her other funded projects.
  b. SCR of renewal applications may also consider the value of continuing a productive project and the contribution this project makes to the investigator's research program and ongoing collaborations.
  c. Consideration may also be given to the PD/PI's field of research when evaluating the appropriateness of awarding new grants above the $1.0M direct cost threshold. The rationales for this consideration are that 1) different types of research (e.g., clinical trials, population sciences) may require larger awards than other fields and 2) non-RPG mechanisms often used for an IC's specialized purposes/goals typically receive separate Council consideration. Since some RPGs, such as U01s, are also used for projects with specialized purposes/goals, each IC, working with its Council, may create defaults for these and other RPG mechanisms or programs to simplify SCR.

NIDDK Implementation of the Second Council Review Policy

Each Council round, the NIDDK Council members will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under the NIH policy as outlined above. During the closed session, for each application on the list that might actually be funded, NIDDK staff will provide information about the other NIH funding for the PI that brings his/her direct cost total to the $1 million threshold and a justification for possibly funding the application under consideration. Council members will review these cases and decide whether or not they have concerns.

Recommendation Process

- NIDDK program staff members examine applications, their overall impact/priority scores, percentile rankings, and their summary statements and consider these against NIDDK's needs.
- Program staff provide a grant-funding plan to the Advisory Council.
- The Advisory Council also considers NIDDK's goals and needs and advises the NIDDK Director.
- The NIDDK director makes the final funding decisions based on staff and Advisory Council advice.

Post-Review

- **Not Funded – What Next?**
  The NIH receives thousands of applications for each application receipt round. Funding on the first attempt is difficult, but not impossible. If an application does not result in funding, NIH has resources available to help applicants prepare a possible resubmission. Applications in response to a specific initiative with set-aside money typically cannot be resubmitted, but the Program Official should be consulted about next steps.

- **Fundable Score – What Next?**
  If an application results in an award, the applicant will be working closely with the NIDDK Program Official on scientific and programmatic matters and a Grants Management Officer on budgetary or administrative issues.

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides access to NIH summary statements. Using World Wide Web and Internet capabilities for database search and retrieval, as an NIDDK Advisory Council member you may read, search, sort, and print any or all of the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB each night, so the ECB is always current.

> ***The data in the ECB, and the codes you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it unattended. Use it and then disconnect. If for some reason you are inactive for approximately one hour, the system will automatically disconnect, and you will have to login again.***

How do I get started?

You or your institution will supply your computer access to the NIH computer, via an Internet connection and a WEB browser (such as Firefox, Netscape Navigator, or Internet Explorer). An NIDDK staff member will give you the information necessary to identify yourself to the NIH computer where the ECB is located. That information includes two codes. The first is called your "USER NAME," the second is your "PASSWORD." Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page**:** https://ecb.nih.gov/council/login.cfm

You will see a screen entitled "**NIH Electronic Council Book**" with two blank boxes for your USER NAME and your PASSWORD. Neither the USER NAME nor the PASSWORD are case sensitive. To log in to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can login to the ECB. To change your password, go to the ECB login page (see below) and click on the link to the "Council Member Change Password Page." Use the NIDDK-issued password as the "Old Password," and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please contact Teresa Lindquist (lindquit@niddk.nih.gov, 301-451-6418).

If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?
When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the "Back" button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option.** There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI's institution.

The Resume Project List retrieves the "Summary of Review and Discussion" section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either "Primary and Dual Projects" or "Dual Projects only" in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator's name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator's last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic,** simply enter the appropriate term in the boxes labeled "Summary Text Contains." This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND, OR*, and *NOT*) to connect two character strings. Note: If one is searching for a topic such as "endocrine disruptors" consider the two words as a single character string and enter both words in the left box separated by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principle Investigator Starts With:" For example, searching for "**Ham"** will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP)**, place **NBH** in the first three boxes. Leave the next box blank and enter OBSP in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

1 New
2 Competing Continuation
3 Supplement
4 Extension
5 Noncompeting Continuation
6 Change of Institute or Division
7 Change of Grantee or Training Institution
8 Change of Institute or Division (noncompeting continuation)

9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).

- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.

- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.

- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND, OR, NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the “Clear Scores” button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2008, the entry would be 01/15/2008 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting "Greater Than or Equal To" from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box 'Foreign Grants' to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 100 to 300 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer's email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note**: Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available. Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a “Zip” file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:
Theresa Smith, smiththe@niddk.nih.gov or 301-443-9908.

Grant Review-Related Policies

Foreign Organizations

In addition to the regular review criteria, foreign applications are evaluated in terms of special opportunities for furthering research programs through the use of special talents, resources (human subjects, animals, diseases, equipment or technologies), populations or environmental conditions in the applicant country which are not readily available in the United States or which provide augmentation of existing United States resources. In addition, it should be noted whether similar research is being done in the United States and whether there is a need for additional research in the area of the proposal. These special review criteria are not applied to applications from domestic institutions that include a significant foreign component.

Research Involving Human Subjects

The rights of all human subjects involved in NIH-supported research are of paramount importance to the Federal Government. Safe-guarding these rights is primarily the responsibility of the institution that receives or is accountable for the funds awarded for support of the research. However, NIH also relies on its scientific review groups (SRGs) and National Advisory Councils or Boards to evaluate all applications and proposals involving human subjects for compliance with the Department of Health and Human Services human subject regulations (Code of Federal Regulations, Title 45 Part 46).

There are several considerations for review of applications involving human subjects. These can be clustered into two broad areas: Protection of subjects from research risks; and the inclusiveness of the study population. Protection issues include questions regarding safety and welfare of the subjects, including data and safety monitoring where applicable. Inclusion issues reflect the appropriate involvement of women, minorities and children.

SRGs assign inclusion codes to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below). The evaluation by Council will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

NIH will fund research covered by the regulations only if the institution has filed an assurance with the Office for Human Research Protections (OHRP) and has certified that the research has been approved by an institutional review board (IRB), a board at the requesting institution formed solely for this purpose.

No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH.

More detailed instructions for reviewing grant applications involving human subjects, and exemptions, are available at the following URL: http://grants.nih.gov/grants/peer/hs_review_inst.pdf.

Definitions:

Human subjects: Federal regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information

derived from individually identifiable human subjects. A subset of research involving human subjects may qualify for exemption, but justification must be provided under the heading "Protection of Human Subjects from Research Risk". The use of autopsy materials is governed by applicable state and local law and is not directly regulated by the Federal human subject regulations.

Clinical research is defined as: (1) Patient-oriented research, i.e., research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. (Excluded from the definition of patient-oriented research are in vitro studies that utilize human tissues that cannot be linked to a living individual.) Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; or (3) Outcomes research and health services research.

A Clinical Trial is operationally defined as a prospective biomedical or behavioral study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions.

An NIH-defined Phase III clinical trial is a broadly based prospective clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

A ***valid analysis*** is required in phase III clinical trials. This means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis are:

- Allocation of study participants of both sexes/genders and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- Unbiased evaluation of the outcome(s) of study participants, and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Research Conducted in a Foreign Country: For foreign awards, and domestic awards with a foreign component, the NIH policy on inclusion of women and minority groups in research is the same as that for research conducted in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

Children: For purposes of this policy, a child is an individual under the age of 21 years. This definition does not affect the human subject protection regulations for research on children (45 CFR 46) and their provisions for assent, permission, and consent, which remain unchanged. State laws define what constitutes a "child," for the purpose of determining whether or not a person can legally consent to participate in a research study.

Exemption from Human Subjects Regulations

If the applicant designates an exemption from the human subjects regulations, reviewers should evaluate the information provided to determine if the designated exemption is appropriate. With regard to exemption 4, although reviewers need not evaluate questions related to research risks or the inclusion of women and minorities, the appropriate inclusion of children ***DOES*** need to be addressed for these applications.

Protection of Human Subjects

If the proposed research involves human subjects, and does not qualify as being exempt, it is considered clinical research (see definition above) and reviewers must evaluate the plan to protect human subjects. The applicant's research plan should include four elements under the heading "Protection of Human Subjects from Research Risk". Reviewers are asked to evaluate each of the four elements:

- ***Risks to the subjects***
- ***Adequacy of protection against risks***
- ***Potential benefit of the proposed research to the subjects and others***.

Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Participants in Research Involving Human Subjects is available at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Women and Minorities in Study Populations

There are clear scientific and public health reasons for including women and minorities in study populations. Accordingly, the NIH requires that applications for clinical research give appropriate attention to including members of these groups in studies. If this is impossible (for example, because the disease occurs only in men or is prevalent only in one racial or ethnic group), or is inappropriate with respect to the health of the subjects, a strong scientific rationale or other well-supported justification is necessary. Unless the rationale/justification is compelling, NIH will not fund such applications. This policy covers research grants, cooperative agreements, and research contracts.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns. These inclusion codes, described below, appear on the summary statement.

Council will consider the degree to which the applicants have addressed this policy when it evaluates applications. Applications with inadequate representation of women and minorities and/or inadequate justification may be deferred, approved based on portfolio considerations, or approved with the condition that staff will ensure compliance with the policy before award. Council will be subsequently notified of awards for these types of approvals.

The NIH will not award research grants, cooperative agreements, or contracts to applicants who do not follow this policy.

Inclusion of Children as Participants in Research

To ensure that adequate data is developed to support the treatment of modalities for disorders and conditions that affect children, as well as adults, it is the policy of NIH that children (i.e., individuals

21 years of age and under) must be included in all human subjects research conducted or supported by the NIH. Children will not be excluded from this policy unless there are scientific and ethical reasons not to include them in the research being conducted; well-supported justification for the exclusion will be necessary. This policy applies to all research involving human subjects, **including** research that is otherwise "exempt". Proposals for research involving human subjects **must** include a description of plans for including children. If children will be excluded from the research, the application must present an acceptable justification for the exclusion.

The section in the application titled "Inclusion of Children" should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan **must** also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Specific exclusionary circumstances and other pertinent information on the inclusion of children in NIH-supported research may be found at: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Use of Human Embryonic Stem Cells In NIH-Supported Research

The National Institutes of Health (NIH) has published final "National Institutes of Health Guidelines for Human Stem Cell Research" (Guidelines).

On March 9, 2009, President Barack H. Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.* The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law.

These Guidelines implement Executive Order 13505, as it pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and helps ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH policies and procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH stem cell research.

EFFECTIVE DATE: These Guidelines are effective on July 7, 2009.

SUMMARY OF PUBLIC COMMENTS ON DRAFT GUIDELINES: On April 23, 2009 the NIH published draft Guidelines for research involving hESCs in the Federal Register for public comment, 74 Fed. Reg. 18578 (April 23, 2009). The comment period ended on May 26, 2009.

The NIH received approximately 49,000 comments from patient advocacy groups, scientists and scientific societies, academic institutions, medical organizations, religious organizations, and private citizens. The NIH also received comments from members of Congress. Read the NIH response to the public comments that addressed provisions of the Guidelines at http://stemcells.nih.gov/policy/Pages/2009guidelines.aspx.

NATIONAL INSTITUTES OF HEALTH GUIDELINES FOR RESEARCH USING HUMAN STEM CELLS

I. Scope of Guidelines

These Guidelines apply to the expenditure of National Institutes of Health (NIH) funds for research using human embryonic stem cells (hESCs) and certain uses of induced pluripotent stem cells (See Section IV). The Guidelines implement Executive Order 13505.

Long-standing HHS regulations for Protection of Human Subjects, 45 C.F.R. 46, Subpart A establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. *When research* involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 C.F.R. 46, Subpart A. Applicants should consult http://answers.hhs.gov/ohrp/categories/1562 .

It is also important to note that the HHS regulation, *Protection of Human Subjects,* 45 C.F.R. Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 C.F.R. § 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidances at http://www.hhs.gov/ohrp/policy/index.html#topics

To ensure that the greatest number of responsibly derived hESCs are eligible for research using NIH funding, these Guidelines are divided into several sections, which apply specifically to embryos donated in the U.S. and foreign countries, both before and on or after the effective date of these Guidelines. Section II (A) and (B) describe the conditions and review processes for determining hESC eligibility for NIH funds. Further information on these review processes may be found at www.NIH.gov. Sections IV and V describe research that is not eligible for NIH funding.

These guidelines are based on the following principles:

1. Responsible research with hESCs has the potential to improve our understanding of human health and illness and discover new ways to prevent and/or treat illness.
2. Individuals donating embryos for research purposes should do so freely, with voluntary and informed consent.

As directed by Executive Order 13505, the NIH shall review and update these Guidelines periodically, as appropriate.

II. Eligibility of Human Embryonic Stem Cells for Research with NIH Funding

For the purpose of these Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. All of the processes and procedures for review of the eligibility of hESCs will be centralized at the NIH according to the guidelines available at http://stemcells.nih.gov/policy/Pages/2009guidelines.aspx.

III. **Use of NIH Funds**

Prior to the use of NIH funds, funding recipients should provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs are listed on the NIH registry.

IV. **Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding**

This section governs research using hESCs and human induced pluripotent stem cells, i.e., human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although the cells may come from eligible sources, the following uses of these cells are nevertheless ineligible for NIH funding, as follows:

A. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
B. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.

V. **Other Research Not Eligible for NIH Funding**

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 3/11/09), otherwise known as the Dickey Amendment.
B. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

   See also: NIH research Involving Introduction of Human Pluripotent Cells in to Non-Human Vertebrate Animal Pre-Gastrulation Embryos: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-158.html

Research Involving Vertebrate Animals

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH relies on its staff, scientific review groups, and Advisory Councils to share this responsibility and review research activities for compliance with the Public Health Service policy for the care and use of vertebrate animals. The general intent of the law and policy can be summarized as two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists;
- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner to avoid any unnecessary discomfort, pain, or injury. Special attention must be provided when the proposed research involves dogs, cats, nonhuman primates, large numbers of animals, or animals that are in short supply or are costly.

Any comments or concerns that scientific review group members may wish to express regarding the appropriateness of the choice of species and numbers involved, the justification for their use, and the care and maintenance of vertebrate animals used in the project will be discussed in a special note in the summary statement. A "concern" is a scientific review group finding regarding animal care or use that requires resolution by program staff prior to award; a "comment" is a scientific review group observation that will be communicated in the summary statement as a suggestion to the principal investigator. For projects involving animals, the species used is separately identified at the end of the "Description" in the summary statement. Any comments or concerns that members have regarding treatment and welfare of research animals used in the project are explained in a separate paragraph in the summary statement. Any questions Council members may have should be directed to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) staff.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below).

No research involving animals may be conducted or supported by NIH until the institution proposing the research has provided a written assurance acceptable to NIH.

Inclusion Codes

Gender, Minority, and Children Codes

An NIH-Defined CLINICAL TRIAL? Y Or N

GENDER CODE	**MINORITY CODE**	**CHILDREN CODE**:
First character = G	*First character* = M	*First character* = C
Second character: 1 = Both Genders	*Second character*: 1 = Minority & Non-minority	*Second character*: 1 = Both children & adults
2 = Only Women	2 = Only Minority	2 = Only children
3 = Only Men	3 = Only Non-minority	3 = No children included
4 = Gender Unknown	4 = Minority Representation Unknown	4 = Representation of children unknown
Third character: A = Scientifically Acceptable U = Scientifically Unacceptable	*Third character*: A = Scientifically Acceptable U = Scientifically Unacceptable	*Third character*: A = Scientifically Acceptable U = Scientifically Unacceptable

Vertebrate Animal Codes

Code 10 No Live Vertebrate Animals Involved

Code 30 Live Vertebrate Animals Involved, no SRG Comments or Concerns
Code 44 Animals Involved - Certified - SRG Concerns
Code 45 Animals Involved - No Assurance - No SRG Comments or Concerns
Code 47 Animals Involved - No Assurance, SRG Comments
Code 49 Animals Involved - No Assurance, SRG Concerns

Biomedical Safety

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the scientific review group in identifying potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

If applications pose special hazards, these hazards will be identified and any concerns about the adequacy of safety procedures highlighted as a special note (**BIOHAZARD**) on the summary statement.

In the case of research involving human immunodeficiency virus, researchers are expected to follow the latest Centers for Disease Control and Prevention recommendations and guidelines for health care workers and laboratory personnel. In research involving recombinant DNA, assessment of an applicant's compliance with Public Health Service guidelines is the responsibility of the NIH Office of Recombinant DNA Activities.

No award will be made until all concerns about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

Advisory Council Policy/Logistical Documents

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Members of Council must return the material given to them to the Executive Secretary at the conclusion of the meeting. All materials members have received at home or at their institutions also must be returned for disposition.

There should be no direct communication between members of Council and applicants. In addition to legal considerations, pre-mature notification of recommendations to applicants often leads to misinterpretation and distortion of discussions and recommendations.

As soon after the Council meeting as possible, applicants will be notified by NIDDK staff about the status of their applications.

Conflict of Interest

NIH takes extreme precautions to avoid placing Council members in situations where there might be an actual or apparent conflict of interest. Thus, at each Council meeting, procedures are delineated to avoid such conflicts.

A member must be absent from the meeting room during review of an application submitted by an institution, or a component of a system of institutions, in which the member or member's spouse, parent, child, partner, or close professional associate is an employee, or in which there is a directive or consultative relationship or financial interest. This includes ownership of stock in, or being a consultant for a for-profit organization. A reviewer should also leave the room during discussion of an application if being present would give the **appearance** of a conflict of interest. Examples would be an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory.

The NIH has been granted a regulatory waiver by the Office of Government Ethics so that faculty of multi-campus institutions of higher education who serve as experts or consultants to DHHS may participate in matters affecting one campus of a state multi-campus institution if the expert's disqualifying financial interest is employment with no multi-campus responsibilities at a separate campus.

Additionally, a Council member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, a recent collaborator, or a close personal friend. Further, a member should not take part in the discussion of an application from a scientist with whom the member has had long-standing differences which reasonably could be viewed as affecting the member's objectivity.

Council members present at each Council meeting sign a statement certifying that they did not participate in the discussion of, or vote on, any application from their own institution or an institution in which they have a financial interest.

Though the staff attempts to identify possible conflicts of interest and bring them to the attention of the Chairperson, the National Diabetes and Digestive and Kidney Diseases Advisory Council needs the assistance of members to ensure that such conflicts do not arise.

Lobbying

Technically, Council members are Government employees and governed by DHHS standards of conduct during the days they are being paid for duty. Thus, during the full midnight-to-midnight period of each of these days, members cannot transact personal business, enter into personal activities with the Legislative or Executive branches of Government, or discuss with NIH staff matters pertaining to their institution's federally funded activities. During this same period, members of Council also must not discuss with members of Congress proposed or pending legislation or appropriations that concern the Public Health Service or DHHS.

Freedom of Information and Privacy Act

The Freedom of Information Act (FOIA) of 1967 and the Privacy Act of 1974 have significantly affected the NIH review and disclosure processes. Under FOIA, a person may obtain access to any Government record, including records about himself or herself, unless the records fall within one of nine exemptions to the Act. The Privacy Act, on the other hand, is limited to records about individuals which are maintained in a "system of records" from which information is retrieved by his or her name or other personal identifier.

For example, under FOIA, third parties may receive copies of awarded grant applications, but they may not received copies of applications that were scored but not funded or applications that were not recommended for further consideration. Also, under the Privacy Act, Principal Investigators may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports and summary statements, but not individual reviews. Reviewers' written comments are not retained after their substance has been incorporated into summary statements or site visit reports.

The Freedom of Information and Privacy Acts

	FREEDOM OF INFORMATION REFORM ACT OF 1986 (P.L. 93-570)	**PRIVACY ACT OF 1974 (P.L. 93-579, DEC. 1974)**
PURPOSE	To allow access by the public to government records.	To provide safeguards for an individual against invasion of personal privacy.
SCOPE	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • methods whereby public may obtain records; • types of records available to the public; • exemptions that permit agencies to withhold certain types of records	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • any system of records from which information is retrieved by an individual's name, identifying number, or other identifying particular assigned to an individual; • any system of records maintained by a government contractor if the agency provides by contract for the "operation by or on behalf of the agency to accomplish an agency function."
REQUIREMENTS	Requires Federal agencies to: • publish in the Federal Register organizational descriptions and locations of agency records; • make all Agency opinions, orders, policy statements, manuals, and instructions available for public inspection and copying; • publish rules stating time, place, fees (as authorized), and procedure to be followed for requesting records; • make records promptly available to any person following the established guidelines for requesting such records; • make available for public inspection a record of the final votes of each member in every Agency proceeding, except as exempted; • release all portions of records not covered by FOIA exemptions. Exemptions that may apply to grants records include those permitting the deletions of commercial information, information that would invade personal privacy, and internal government options and advice.	Requires Federal agencies to: • permit individuals to determine what records pertaining to them the agency collects, maintains, uses, or disseminates; • permit individuals to prevent records pertaining to them obtained for a particular purpose from being used or made available for another purpose without their consent; • permit individuals to gain access to information pertaining to them in agency records, to have a copy made of their records, and to correct or amend their records; • collect, maintain, use, or disseminate records of identifiable personal information in a manner that assures that such action is for a necessary and lawful purpose, that the information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of information; • be subject to civil or criminal sanctions as a result of willful or intentional actions which violate any individual's rights under the Act; • publish annually a notice in the Federal Register indicating the existence and character of the system records..
SUMMARY	Makes possible disclosure of policy, procedures, and records to the public.	Safeguards the privacy of individuals in the face of disclosure.

Travel Procedures for NIDDK Advisory Council Members

When you travel to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meeting, **you are considered a Government employee** of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and therefore traveling on official Government business. Your expenses are reimbursed according to Federal travel regulations.

In order for you to be reimbursed in a timely manner and to ensure that you will be reimbursed for your travel expenses, please be sure to read the information below.

Note: If you will **not be attending** the meeting, please call Dr. Brent Stanfield at (301) 594-8843 to inform him of your absence.

Overview of Expenses and Reimbursement

Allowable consultant expenses for members of NDDKAC are as follows:
Air/Rail Transportation. Round-trip transportation (from home to Bethesda, Maryland, and back).

Ground Transportation. This includes costs for taxis (including a 15 percent tip), shuttle services, parking, tolls, subway fare, and any other reasonable transportation costs.

Travel by Privately Owned Vehicle. If you drive your car to the meeting or to the airport, you will be reimbursed for the miles, tolls, and parking expenses incurred. The current Government rate is $0.565 per mile.

Hotel. You will be reimbursed for the Government room rate and associated taxes.

Meals and Incidental Expenses (M&IE). This is a fixed rate, currently $71.00 per day for the Washington, D.C., metropolitan area. You will receive ¾ of the M&IE rate for a maximum of 2 travel days. For any non-travel days spent at the meeting, you will receive the full per diem less any meals provided.

Honorarium. You will receive a $200.00 honorarium for each day or fraction of a day that you attend the Advisory Council meeting. These checks are processed separately using Electronic Funds Transfer.

Travel Instructions

NIDDK will fax an NIH travel order to you prior to your travel.

Per Federal travel regulations, all Government employees are required to use their agency's travel management center. Therefore, **you are required to book your air or train fare through Omega World Travel (OWT) and you must book coach class.** Please mention you are attending the "NIDDK Advisory Council Meeting on_____(date)_____in Bethesda, Maryland.

It is the Council member's responsibility to contact Omega Travel at 866-264-8281 (for after-hours emergencies please contact 800-285-6342) to confirm/change the travel reservation. OWT's local number is 301-984-8985' fax is 301-984-9552. .All airline tickets will be processed as electronic tickets. When using Omega World Travel, the ticket will be paid for by the National Institutes of Health. When air/rail transportation is used, travelers must use the most economical means. All travel should be by the most direct route.

What do I need to do to make a change on my airfare so I can be reimbursed for additional expenses due to changes?

If you need to make a change on your airfare, you are required to contact OWT (see phone number s above). **We recommend that you carry their after hours number with you in case you need to make a change to your airfare or train ticket.**

What if I don't contact OWT? How will this affect my reimbursement?

Please note that if you book either business class for airfare and/or a train ticket, you will not be reimbursed. In addition**, you can not pay the difference for a change in your airfare or train ticket by paying the additional money in cash.** Again, you must contact OWT; they will charge additional travel expenses to our government account. *Travelers who choose to not use Omega World Travel to make their travel reservations will not be reimbursed by NIH/NIDDK.*

Will I receive a confirmation from OWT of my airfare or train ticket reservations?

Yes. OWT will process your reservation with an electronic ticket and send you a confirmation notice via email. Retain this confirmation number.

Can I be reimbursed for rental car expenses?

Rental car expenses are rarely approved and must be pre-approved on the travel order. Under no circumstances will rental care expenses be reimbursed without prior authorization.

Can I be reimbursed for the expense of using a sedan instead of a taxi

You can always be reimbursed for taxis but not for use of a sedan.

What documents should I carry with me when I travel?

- OWT's phone numbers in case you need to make a change in your itinerary

OMEGA WORLD TRAVEL After hour's emergency: (800) 285-6342 Outside the local area: (866) 264-8281 Local Area: (301) 984-8985 Fax: (301) 984-9552

- A **government-issued photo ID** (license, passport, etc.)
- A **copy of your electronic ticket** with confirmation number.
- The **NIH travel order** to verify that you are traveling on official Government business. NIDDK will fax the travel order to you prior to your travel.

Hotel Information

NIH/NIDDK books and pays for hotel rooms for all Council members. Hotel room confirmation numbers will be submitted to you prior to your departure. Also please confirm your check-in and check-out dates, especially if arriving late. You will be lodging at the Hyatt Regency Bethesda.

Hyatt Regency Bethesda
7400Wisconsin Avenue
Bethesda, MD 20814
T: (301) 657-1234
F: (301) 657-6453
http://bethesda.hyatt.com/en/hotel/home.html?src=agn_mls_hr_lclb_blocal_bethe

Expense Reimbursement

After completion of travel, Council members must file a Travel Expense Form (sample attached). It is necessary to include:

- Travel stubs or the travel itinerary showing the price of the ticket
- Other travel related receipts over $75.00 (e.g., receipts for taxi fares, tolls, parking fees)
- Original hotel bill
- Rental car receipt (reimbursement must be pre-approved).

Travelers are reimbursed for three-quarters of a day's per diem on arrival and departure days. No receipts are needed. (See M&IE above.)

Travel Expense forms and receipts should be sent within 5 days of your complete travel to:

Clairisse Mullsteff, Program Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 713B
6707 Democracy Boulevard
Bethesda, MD 20892-5452

Once your completed Travel Expense Form with all receipts attached is received, you will be sent a travel voucher for your signature. The travel voucher is a document prepared at the conclusion of your trip itemizing all claims for reimbursement.

After the travel voucher is received at NIH, the payment will be deposited into your banking account within 14 business days in the amount indicated on the travel voucher as "NET TO TRAVELER."

Note: Your honorarium will be processed separately as noted above.

If you have any questions, please do not hesitate to contact Clairisse at 301-594-8843 or email her at mullsteffcy@mail.nih.gov.

NIDDK ADVISORY COUNCIL TRAVEL EXPENSE FORM

(_____(date) _____Council Meeting)

REQUIRED RECEIPTS: (Please attach to this form)

- **Travel Stubs/Itinerary** with total price of ticket $_____
- **Original Hotel** itemized receipt:
  - Room Rate $_____
  - Hotel Taxes $_____
  - Phone Calls ($5.00 per day are reimbursable) $_____
- Other travel-related receipts **over $75.00** $_____
- Rental car (reimbursement must be pre-approved) $_____

OTHER REIMBURSEABLE EXPENSES:

- Privately-Owned Vehicle (Number of Miles x $0.565 cents)
  $_____
- Parking Fees $_____
- Taxis:
  - From Residence to Terminal $_____
  - From Terminal to Hotel $_____
  - From NIH Campus to Terminal $_____
  - From Terminal to Residence $_____
  - Other $_____
- Tolls $_____
- Other miscellaneous expenses $_____

  (Please describe:_____)

DO NOT CLAIM ANY MEALS FOR REIMBURSEMENT. The amount of Meals and Incidental Expenses (M&IE) reimbursed is set at a fixed rate of $71.00per day while you are on official government business. You will receive ¾ of the M&IE rate for each day you are in travel.

PRINT NAME: _____

SIGNATURE: _____

DATE: _____

RESPONSIBILITIES OF NIDDK ADVISORY COUNCIL MEMBERS

(A Cheat Sheet for New NIDDK Council Members)

I. Before the meeting

Early Concurrence

- All grant applications (excluding those from foreign organizations) which have no concerns noted that would represent a bar to award (e.g., for human subjects, animal welfare, biohazards, etc.) or need Special Council Review, will follow an expedited concurrence process.
- A few weeks prior to the meeting NIDDK will alert the early concurrence committee members that these applications are available in the Electronic Council Book (ECB).
- As a new member it is unlikely that you will be asked to be a member of the early concurrence committee, but during this process all Council members are provided the list of all applications eligible for early concurrence for review and any member may bring any of these applications to full Council consideration.

Bottom line: *You may wish to spend a little time looking over the early concurrence list to see if you have any concerns--and if you do let Brent Stanfield know A.S.A.P.*

Council Materials

- About ten days before the Council meeting Council Members are notified that materials for the meetings are available for their review.
- These materials are available via the ECB using the same access information that was earlier given for access to the early concurrence list.
- Scientific members are frequently asked in advance to review particular applications or proposed actions in the closed portion of the subcommittee meeting, and they are often provided additional materials.

Bottom line: *Please thoroughly review these materials prior to the meeting & contact the appropriate NIDDK Division Director if you have any concerns or if you would like additional information.*

Additional Requests

- Occasionally a Division Director, or other NIDDK staff member, will contact a Council member to request that they participate as a discussant of a presentation at an open portion of the meeting.
- If available, the slide set or additional materials will usually be provided to the Council member.

Bottom line: *Please review these materials & come to the meeting prepared to participate as requested. Please be sure that you understand & follow any specific guidance — especially when considering appeals. NIDDK needs advice on the merit of the appeal, not the merit of the application.*

Attendance

- Members are encouraged to attend the entire Council meeting. Staff will work with you or your assistant to arrange travel plans that will allow you plenty of time to catch your flight after the meeting.

Bottom line: *Please don't plan on leaving Council meetings early.*

II. At the meeting

Closed Sessions

- Council members are requested to come prepared to fully participate in the closed sessions.
- Members are reminded that all matters discussed or materials available for discussion in closed sessions and the discussions themselves are confidential and should not be shared with anyone outside of the meeting.

Bottom line: *What happens in closed session stays in closed session.*

Open Sessions

- Council members are requested to come prepared to participate fully in the open sessions, including the discussions that follow presentations.
- Members are encouraged to provide specific feedback to NIDDK staff about any of the matters discussed or potential matters or issues they would like to hear discussed at a future meeting.
- Remember that ***members of the public, of advocacy groups, and of the press may attend our Council meetings*** and anything that you say in the open sessions of Council meetings could be reported.

Bottom line: *Please interact & give us your perspective and advice, but be careful about seeming/being too prescriptive in open session and also please be careful in open session not to say anything that you (and we) might regret if it gets reported and appears in print.*

III. After the meeting

Special Requests

- Occasionally Council members may be requested to review certain matters (for example, an appeal that arrived too late for consideration at the meeting) after the meeting.
- Please provide the requested advice within the timeframe allowed and treat all of these matters as confidential, just as you would were they are being considered within closed session.

Bottom line: *These matters are essentially an extension of the closed session.*

What do we really want from you?

- Your scientific expertise
- Your understanding of patient and clinical issues
- Your wise council about our general portfolio
- Your thoughts about NIH/NIDDK policies, the public landscape and help in avoiding pitfalls
- Your outreach and advocacy on behalf of NIH/NIDDK both within your community and to the public to explain the processes, the considerations, the rigor, and the fairness of how we do business and the important work that we support
- Your help in keeping NIDDK at the cutting edge of science and scientific administration

What should you be careful about?

- Keeping closed session materials and discussions confidential
- Paying attention to and avoiding/disclosing any real or apparent conflicts of interest as soon as they arise

- Advocating to elected officials while on official government travel
    - You are a special government employee when you are traveling to attend Council meetings and during this time you are not allowed to advocate!
- Keeping in mind that anything you say in the open sessions of the Council meeting (both the main sessions and open sessions of the sub-councils) could wind up in print
- Not appearing to be too prescriptive in your remarks – You represent NIDDK's broad community rather than advocating for a particular segment of that community
    - Sparking disease or research area wars is not in anyone's best interest

NIDDK Advisory Council Orientation Reference Links
January, 2015

General background information about Council

- **Advisory Council page on the web:**
  http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/Pages/advisory-council.aspx
- **Advisory Council Charter:**
  http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/Documents/2012NIDDKChartersigned.pdf
- **Advisory Council Operating Procedures:**
  http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/operating-procedures/Pages/operating-procedures.aspx
- **Advisory Council Membership Roster:**
  http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/members/Pages/advisory-council-members.aspx

General background information about NIDDK and funding

- **NIDDK Mission:**
  http://www.niddk.nih.gov/about-niddk/meet-the-director/mission-vision/Pages/mission-vision.aspx
- **NIDDK Organization:**
  http://www.niddk.nih.gov/about-niddk/offices-divisions/Pages/default.aspx
- **NIDDK Division of Extramural Activities:**
  http://www.niddk.nih.gov/about-niddk/offices-divisions/division-extramural-activities/Pages/default.aspx
- **NIDDK Division of Intramural Research:**
  http://www.niddk.nih.gov/about-niddk/offices-divisions/division-intramural-research/Pages/default.aspx
- **NIDDK Funding Policy:**
  http://www.niddk.nih.gov/research-funding/process/award-funding-policy/Pages/award-funding-policy.aspx

Administrative matters regarding Council membership

- **Confidentiality, Conflict of Interest & Lobbying**
  (Ethics Training for Special Government Employees):
  http://oge.gov/Education/Education-Resources-for-Federal-Employees/Ethics-Training-for-Special-Government-Employees-WBT/
- **Procedures for Avoiding Conflict of Interest for Special Government Employees:**
  http://oma1.od.nih.gov/manualchapters/management/1810-1/

- **Travel Reimbursement:**
  http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/travel-expenses-reimbursement/Pages/advisory-travel-expenses-reimbursement.aspx

The Grant Process

- **NIH Grants Process Overview, from application to award:**
  http://grants.nih.gov/grants/grants_process.htm
- **Types of NIH grants:**
  http://grants.nih.gov/grants/funding/funding_program.htm
- **About Funding Mechanisms, including information about how NIDDK utilizes certain funding mechanisms:**
  http://www.niddk.nih.gov/research-funding/process/apply/about-funding-mechanisms/Pages/AboutFundingMechanisms.aspx
- **Peer Review Policies & Practices:**
  http://grants.nih.gov/grants/peer/peer.htm

Grant Policies & Regulations

- **FOIA & Privacy:**
  http://www.nih.gov/icd/od/foia/5usc552.htm
  See also: http://www.niddk.nih.gov/Pages/niddk-privacy-statement.aspx
- **NIH Grants Policy & Guidance:**
  http://grants.nih.gov/grants/policy/policy.htm
- **NIH Intellectual Property Policy:**
  https://grants.nih.gov/grants/intell-property.htm
- **NIH Invention Reporting (iEdison):**
  https://s-edison.info.nih.gov/iEdison/
- **NIH Public Access Policy:**
  http://publicaccess.nih.gov/
- **NIH Genomic Data Sharing Policy:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html
- **Research Integrity/Research Misconduct:**
  https://grants.nih.gov/grants/research_integrity/index.htm
- **Information about NIH grant applications from foreign countries:**
  http://grants.nih.gov/grants/foreign/index.htm
- **Simplified NIH Policy for Late Application Submission:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html

- **New Biographical Sketch Format required for grant applications submitted for due dates on or after May 25, 2015:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html

Additional Information

- **Information for new Council Members:**
  http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/Documents/NIDDKACOrientationHandbook508cRev02112012.pdf

Recent Notices in the Guide on Changes to Policy, etc.:

- **Use of updated Inclusion enrollment format now required for successful submission of RPPR:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-078.html

- **Notice of update to the Public Health Service policy on Humane Care and Use of Laboratory Animals:**
  https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-079.html

- **Consideration of Sex as a Biological Variable in NIH-funded Research:**
  https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html

- **Guidance on changes that involve Human Subjects in active awards and that will require prior NIH approval: Updated Notice:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html

- **Prior NIH approval of Human Subjects Research in active awards initially submitted without definitive plans for Human Subject involvement (delayed onset awards): Updated Notice:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-129.html

- **Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html

- **NIH & AHRQ announce new form for PHS awarding component and peer review requests:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-008.html

- **Inclusion of Children in Clinical Research: Change in NIH Definition:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html

- **Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-012.html

- **Clarifying NIH priorities for Health Economics Research:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-025.html

- **Updates to NIH & AHRQ Research Performance Progress Reports (RPPR) to address Rigor and Transparency:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-031.html


National Institute of
Diabetes and Digestive
and Kidney Diseases